Package leaflet: Information for the patient

Naloxone Hydrochloride 400micrograms/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 referred to as Naloxone Injection/Infusion for ease hereafter.

What is in this leaflet

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

Naloxone belongs to a group of medicines known as opioid antagonists. 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/Infusion may be used:
- to treat the breathing problems caused by these 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 infants (resulting from the use of opioid painkillers in the mother during childbirth).

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

You should not be given Naloxone 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 you are given Naloxone Injection/Infusion. Your doctor will take special care if:

- you have received large doses of opioid drugs or if you have a drug-dependence (drug addiction) problem.
- you suffer from any heart or circulatory problems.
- you suffer from high blood pressure, irregular heart beat or difficulty in breathing.
- you have a newborn baby who requires this injection/infusion; tell the doctor beforehand if you received large doses of opioid drugs before you gave birth or if you have a drug-dependence problem.
- you are suffering from diseases of the kidney, liver or lung.

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.

Other medicines and Naloxone Injection/Infusion
Tell your doctor if you are taking or have recently taken or might take any other medicines.

A number of medicines can interact with Naloxone Injection/Infusion which can significantly alter their effects. In particular, tell your doctor if you are taking

- Strong pain killer medicines like buprenorphine and pentazocine.
- Sleeping pills
- Medicines that may affect your heart or blood circulation (e.g. antihypertensive drugs, cocaine, methamphetamine, cyclic antidepressants, calcium channel blockers, beta-blockers, digoxin and clonidine) even those not prescribed.

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.
The potential risk for humans is unknown. Naloxone Injection/Infusion should not be used during pregnancy unless clearly necessary.
Naloxone Injection/Infusion must be used with caution in breast feeding mothers. Breast-feeding should be avoided for 24 hours after treatment.

Driving and using machines:
After receiving Naloxone Injection/Infusion, 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.

Important information about sodium content in Naloxone Injection/Infusion

This medicine contains 88.2 mg sodium (main component of cooking/table salt) in maximum daily dose of 10mg naloxone hydrochloride. This is equivalent to 4.4% of the recommended maximum daily dietary intake of sodium for an adult.

3. How Naloxone Injection/Infusion is given to you

Naloxone Injection/Infusion is always given by a doctor or nurse.
It may be injected into a vein, a muscle, or the tissue just under the skin. It may also be given by a drip into a vein.
The dose of the injection/infusion will be calculated by your doctor. This will depend upon your weight and the circumstances that require treatment.

For adults:
•To treat an overdose or suspected overdose of opioids, between 400 and 2000 micrograms may be given every 2-3 minutes.
•After an operation 100-200 micrograms may be given every 2-3 minutes.

For children:
•The usual dose is 10 micrograms for each kilogram they weigh increased to 100 micrograms per kg to achieve the desired response.

For new born babies:
•The usual starting dose is 10 micrograms per kg body weight every 2-3 minutes. Or a single dose of 200 micrograms may be given at birth.

If you think you have been given more Naloxone Injection/Infusion than you should have
This is unlikely as your injection/infusion will be administered by a doctor or nurse. If you are concerned about the dose, discuss it with 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.

Other side effects may include:

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

Common: (may affect up to 1 in 10 people)
- Dizziness
- Headache
- Fast Heart beat
- Increased or decreased blood pressure
- Vomiting
- 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)

- Tremors
- Sweating
- Changes in the way your heart beats
- Slow heart rate
- 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)

- Fits (seizures)
- Tension

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

- Severe problems with the heart(Fibrillation and cardiac arrest)
- Fluid in the lungs
- Discolouration and lesions of the skin.
- Allergic reactions (urticaria, rhinitis, dyspnoea, Quincke's oedema), anaphylactic shock

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

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
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 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 carton and ampoule label after 'Exp'. The expiry date refers to the last day of that month.
Do not store above 25°C.
Keep the ampoules (small bottles) in the outer carton in order to protect from light.

If only part used, discard the remaining solution.
Do not use the ampoule if the contents are discoloured in any way.
For single use only.
Do not throw away any medicines via wastewater . 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

The active substance is naloxone hydrochloride dihydrate. The other ingredients are sodium chloride, dilute hydrochloric acid (for pH adjustment) in water for injections.

What Naloxone Hydrochloride Injection/Infusion looks like and contents of pack

Naloxone Hydrochloride 400micrograms/ml Solution for Injection/Infusion (0.4 mg/ml) is a clear, colourless, sterile solution containing 400 micrograms (0.4mg) naloxone hydrochloride present as naloxone hydrochloride dihydrate in 1ml clear glass ampoules (small bottles).
Pack size: 3, 5 or 10 ampoules may be packaged together in cardboard cartons. All pack sizes may not be marketed.

Marketing authorisation holder:

Mercury Pharmaceuticals Ltd,
Dashwood House, 69 Old Broad Street,
London, EC2M 1QS, United Kingdom

Manufacturer: Delpharm Tours, Rue Paul Langevin, 37170, Chambray-Les-Tours, France.

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