PACKAGE LEAFLET: INFORMATION FOR THE USER

D04873

Naloxone Hydrochloride 1mg/ml Solution for Injection in a pre-filled syringe

Naloxone Hydrochloride

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Because of your condition it may not be possible for you to read this leaflet before you are given Naloxone Hydrochloride Injection. The leaflet has been provided to you to give some information that you should have. You may wish to read it later.
- If you have any further questions, please ask your doctor or nurse
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Naloxone Hydrochloride Injection is and what it is used for

Naloxone belongs to a group of medicines that reverse the action of opioid drugs e.g. morphine.

This medicine is used to:
- reverse the action of opioid drugs e.g. if you have been given or taken an overdose of these drugs.
- reverse the action of opioids given during surgery.
- allow a newborn baby to breathe following birth if opioids have been given to the mother during childbirth.

2. What you need to know before Naloxone Hydrochloride Injection is given

This medicine is often used in circumstances where the doctor may need to act very rapidly. You will not be given this medicine unless your doctor feels it is absolutely necessary.

You should not be given Naloxone Hydrochloride Injection if:
- you know you are allergic to Naloxone Hydrochloride or any of the other ingredients of this medicine (listed in section 6).

Your doctor will take special care with Naloxone Hydrochloride Injection if:
- you have taken or been given a large dose of opioid drugs or if you have a drug-dependence (drug addiction) problem
- you have kidney, liver or lung problems
- you have heart or circulatory problems
- you suffer from high blood pressure, irregular heart beat or difficulty in breathing.

If you have taken or been given a dose of opioid drugs and have just given birth, your doctor will take special care in giving naloxone to your baby.

Your doctor will be able to advise you on your particular situation.

Other medicines and Naloxone Hydrochloride Injection
If you are able, tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines, including those obtained without a prescription.

A number of medicines can interact with Naloxone Injection 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, betablockers, digoxin and clonidine) even those not prescribed.

Pregnancy and breast-feeding
Tell your doctor before you are given this medicine if you are pregnant, think you may be pregnant or are planning to become pregnant, or are breast-feeding.
The potential risk for humans is unknown.
Naloxone should not be used if you are pregnant or breast-feeding unless it is absolutely essential.
Naloxone Hydrochloride Injection must be used with caution in breast feeding mothers. Breast-feeding should be avoided for 24 hours after treatment.

Driving or using machines
This medicine can affect your ability to drive and operate machinery. Do not drive, operate machinery or engage in other activities demanding physical or mental exertion for at least 24 hours if you feel drowsy or cannot think clearly.

Naloxone Hydrochloride Injection contains Sodium
This medicinal product contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially 'sodium- free'.

3. How Naloxone Hydrochloride Injection will be given

The doctor or nurse will administer the injection slowly into a vein (intravenously by injection or as a drip), into a muscle (intramuscularly), or under the skin (subcutaneously). The dose depends on individual needs and responses to the treatment.

Adults
Known or suspected opioid overdose:
An initial dose of Naloxone Hydrochloride Injection will be given intravenously. If there is no improvement in your condition you may receive further doses at 2 to 3 minute intervals. If the injection cannot be given into a vein, then it may be given in the muscle or under the skin.

Following surgery:
The dose will be adjusted to your individual needs to ensure you can breathe comfortably while maintaining adequate pain relief. Usually the initial dose will be given intravenously followed by further injections into the muscle if required.

Children and newborns
The dose will be adjusted to the child or baby's needs. The injection may be given into a vein, muscle or under the skin. Additional doses may be given at different intervals.

You or your child will be closely monitored during treatment.

If you are given more or less Naloxone Hydrochloride Injection than you should have
This medicine will be given to you in hospital and it is unlikely that you will be given too little or too much. However, tell your doctor if you have any concerns.

4. Possible side effects

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 less than 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

Reporting of side effects
If you or your child gets 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 via the Yellow Card Scheme at 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 Hydrochloride Injection

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

You should not be given Naloxone Hydrochloride Injection after the expiry date which is printed on the box. The doctor or nurse will check the expiry date on the label before administering the injection to you.

Store in the original box in order to protect from light.

Do not store above 25°C.

If only part used, discard the remaining solution
For single use only.

6. Contents of the pack and other information

What Naloxone Hydrochloride Injection contains.
The active ingredient is Naloxone Hydrochloride 1mg per ml.
The other ingredients are Sodium Chloride, Water for Injection and Dilute Hydrochloric Acid.

What Naloxone Hydrochloride Injection looks like and contents of the pack.
The injection is supplied in a 2ml prefilled syringe containing 2ml of a clear, colourless solution. The syringe is contained in a box.

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