

Patient Information Leaflet: Naloxone Hydrochloride Minijet, 400 micrograms/ml solution for injection naloxone hydrochloride

Read all of this leaflet carefully before you are given this medicine.

- Keep this leaflet. You may need to read it again
- If you have any further questions, ask your doctor or nurse

In this leaflet, Naloxone Hydrochloride Minijet 400 micrograms/ml solution for injection will be called Naloxone.

In this leaflet:

1. What Naloxone is for
2. Before you are given Naloxone
3. How Naloxone will be given to you
4. Possible side effects
5. How to store Naloxone
6. Further information.

1. What Naloxone is for

Naloxone belongs to a group of medicines called "opioid antagonists." It counteracts strong painkillers (opiates).

Naloxone is used to restore the body's breathing if it has been affected by strong painkillers (usually opioids such as morphine, heroin, methadone etc.) which may have been given during an operation for example.

It is also used for the same reason after an overdose of these drugs has been taken, or when an overdose of opioids is suspected.

As Naloxone is only used in medical emergencies, the injection will be given by a doctor or nurse in a hospital.

2. Before you are given Naloxone

Do not use Naloxone if:

- You are allergic to Naloxone
- You are allergic to any of the other ingredients in Naloxone (see section 6)

If this applies to you talk to your doctor or nurse.

Check with your doctor before you are given

Naloxone if:

- You are addicted to heroin or similar drugs
- You have heart or circulation problems
- You are pregnant, planning pregnancy or breast-feeding
- You have just had an operation

Tell your doctor if you are taking any of the following medicines:

- Medicines that may affect your heart
- Any other medicine, including medicines obtained without a prescription.

Pregnancy and breast-feeding

Tell your doctor if you are pregnant, trying to become pregnant or breastfeeding.

Naloxone will only be given to you if your doctor considers the benefit of treatment outweighs the risk to the developing or new born baby.

3. How Naloxone will be given to you

Important:

- **Naloxone will be given to you by a doctor or nurse. Your doctor will choose the dose that is right for you**
- The dose depends on how much you need to reverse the effects on your breathing. The following is a guide.
- Naloxone is always given by injection by a doctor or health professional, usually into a blood vessel. It may be given slowly through a drip. It can be given into a muscle or under the skin.

Adults and the elderly

- 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.

Children

- The usual dose is 10 micrograms for every kg they weigh increased to 100 micrograms per kg if there is not a good enough response.

Patients are monitored to make sure the effect of the Naloxone lasts as long as the drugs it is counteracting. Additional doses may be given every 1-2 hours if necessary.

If you think you have been given more Naloxone than you should

As this medicine will be given to you by a doctor or nurse, it is unlikely that you will be given too little or too much. However, if you think you have been given too much of this medicine, please tell your doctor.

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

4. Possible side effects

Like all medicines Naloxone can cause side effects, although not everybody gets them.

It may be difficult to know what side effects Naloxone has because it is always given after other drugs have also been used.

Side effects include:

- Feeling sick or being sick
- Tremor, sweating
- Over breathing (associated with an abrupt return to consciousness)
- Fast heart beat or disturbed heart rhythm
- Increased or decreased blood pressure (you may have a headache or feel faint)
- Fluid on the lungs
- Fits
- If Naloxone is given to people addicted to heroin or similar drugs, it can cause an acute

withdrawal syndrome. This can also happen to babies born to opioid-dependent mothers. The sudden reversal of narcotic depression when naloxone is taken may cause violent behaviour

- If too large a 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

Ireland

HPRa Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2;

Tel: +353 1 6764971;

Fax: +353 1 6762517.

Website: www.hpra.ie;

E-mail: medsafety@hpra.ie.

United Kingdom

Yellow Card Scheme

Website: 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 out of the reach and sight of children.

Do not use this medicine after the expiry date on the carton and vial label. The expiry date refers to the last day of that month.

Store below 25°C.

Keep the glass syringe in the outer carton to protect from light.

Single use only. Discard and unused contents.

Your doctor or nurse will make sure your medicine is correctly stored and disposed of.

6. Further information

What Naloxone contains

The active substance is naloxone hydrochloride (as the dihydrate). There are 400 micrograms per ml.

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

What Naloxone looks like

Naloxone is a sterile solution. It comes in 3 different pack sizes as follows:

1 ml clear glass syringe with a luer-lock

2 ml clear glass syringe with an integral 1.25 inch needle

5 ml clear glass vial with a separate injector. Not all pack sizes may be marketed.

Marketing Authorisation Holder

DLRC Pharma Services Limited, Chesterfield House, Clonmannon, ASHFORD, County Wicklow, A67WR29, Ireland

Manufacturer

UCB Pharma Limited, 208 Bath Road, Slough, Berkshire, SL1 3WE, UK

This leaflet was last updated **January 2019**.

If this leaflet is difficult to see or read or you would like it in a different format, please contact: DLRC Pharma Services Limited, Chesterfield House, Clonmannon, ASHFORD, County Wicklow, A67WR29, Ireland