

A leaflet will be included in each pack. The leaflet will consist of a Technical Information Leaflet and a Patient Information Leaflet. The two leaflets will be easily separable. The text of the Technical Information Leaflet will be consistent with the approved SmPC. The text of the Patient Information Leaflet will be as follows:

Package leaflet: Information for the patient

Naloxone Hydrochloride 20 micrograms / ml Solution for Injection

Naloxone hydrochloride

Read all of this leaflet carefully before your medicine is administered because it contains important information for you.

- Keep this leaflet. You may want to read it again.
- If you have any questions, ask your doctor, pharmacist 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 is and what it is used for
2. What you need to know before you are given Naloxone Hydrochloride
3. How Naloxone Hydrochloride is given to you
4. Possible side effects
5. How to store Naloxone Hydrochloride
6. Contents of the pack and other information

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

Naloxone hydrochloride is a narcotic antidote that can be used to reverse the effects of an overdose. This can be useful in diagnosis of a suspected overdose.

Narcotic (or opiate) drugs, in overdose, cause breathing difficulties. Naloxone hydrochloride is used to reverse this effect. This particular dose of Naloxone hydrochloride can help treat asphyxia (an inability to breathe) after someone has received a narcotic drug during labour. It can be used to reverse the depressant effects on breathing 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 Hydrochloride

Do not use Naloxone Hydrochloride if:

You are allergic to naloxone hydrochloride or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

If you are given naloxone hydrochloride for treatment of acute opiate overdose, you may need to be given other drugs, or a tube placed in your throat, to help you breathe and ensure that your blood circulation continues.

If you have heart disease or are taking drugs known to be harmful to the heart, naloxone may cause further heart problems. Your doctor, and other medical staff looking after you, will know about this and try to keep this under control.

Speak to your doctor if this applies to you before you are given this medicine.

The effects of some opiates last longer than the effects of naloxone hydrochloride. You may need to be given further doses.

If you are addicted to opiates you may experience withdrawal symptoms when you are given naloxone hydrochloride.

Speak to your doctor if this applies to you before you are given this medicine.

Naloxone is not effective for breathing difficulties not due to opioid drugs.

Children

Withdrawal symptoms may occur in the newborn children of addicted mothers.

Other medicines and Naloxone Hydrochloride

No drugs should be added to solutions containing naloxone unless compatibility is known. Naloxone should not be mixed with preparations containing bisulphate, metabisulphate, long chain or high molecular weight anions or those with an alkaline pH.

Pregnancy and breast-feeding

If you are pregnant: It is not known if Naloxone Hydrochloride is harmful to the unborn child. Naloxone Hydrochloride will only be given to you if it is absolutely essential. Ask your doctor or nurse for advice before you are given this medicine.

If you are breast feeding: It is not known if naloxone hydrochloride appears in breast milk. Ask your doctor or nurse for advice before you are given this medicine.

Naloxone Hydrochloride contains sodium

This medicine contains 9 mg/ml of sodium. Please speak to your doctor if you are on a strict sodium-controlled diet.

3. How Naloxone Hydrochloride is given to you

It is usually given by injection into a vein (intravenous or IV). If this is not possible it may be injected into a muscle (intramuscular injection or IM) or just beneath the skin (subcutaneous injection or SC). Sometimes naloxone may be diluted and given as an infusion (drip).

The following is listed as a guide. Your doctor may decide that you need more or less than the dose of naloxone hydrochloride indicated here.

Use in Children

Opioid overdose - known or suspected: The usual initial dose in children is 10 micrograms/kg body weight given intravenously. If this does not have the desired effect a further dose of 100 mcg/kg body weight may be given.

Postoperative opioid respiratory depression: In children the initial dose of naloxone for reversal of respiratory depression should be in increments of 5-10 micrograms (0.25-0.5 ml of 20 microgram/ml strength) intravenously at 2 to 3 minute intervals. The time interval and dose will depend on response to the injection.

Use in the Newborn

Narcotic induced depression: The usual initial dose is 10 micrograms/kg body weight administered intravenously or alternatively, by intramuscular or subcutaneous injection. This dose may be repeated and will depend on response to the injection.

How long you will be given Naloxone Hydrochloride for?

You will only be given naloxone until your breathing improves.

If you receive more Naloxone Hydrochloride than you should

The effects of naloxone, on its own, in overdose are not known. You will be given naloxone by a doctor or paramedic and it is unlikely that you will be given an overdose. If naloxone hydrochloride is given too quickly, or in too high a dose, to patients who have been given or have taken opiate drugs the following effects may occur:-

- excitement
- increased blood pressure
- pain killing effect of opiate drugs is lost
- nausea
- vomiting
- sweating
- palpitations

If a dose of Naloxone Hydrochloride is missed

Again this is unlikely as you will be given naloxone hydrochloride injection by a doctor or paramedic. Your doctor may decide to miss, delay or reduce a dose, depending on your response to the treatment.

If you stop using Naloxone Hydrochloride

The effects of naloxone hydrochloride are shorter than the effects of some of the opiate drugs. The effects of the opiate drug may reappear, and you may need to be given further doses of naloxone hydrochloride.

If you are addicted to opiate drugs naloxone hydrochloride may cause symptoms of opiate drug withdrawal.

4. Possible side effects

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

In patients with heart disease the following may occur:-

- increased blood pressure
- fluid on the lungs
- irregular heart beat
- heart attack

If you notice any difficulty in breathing, palpitations or pains in your chest tell your doctor or nurse.

As indicated above, if too much naloxone is given, or if it is given too quickly the following symptoms may occur:

- excitement
- increased blood pressure
- pain killing effect of opiate drugs is lost
- nausea
- vomiting
- sweating
- palpitations
- tremor
- over breathing (hyperventilation)

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)

Fast heart beat

Increased blood pressure

Vomiting

Uncommon: (may affect up to 1 in 100 people)

Tremors

Sweating

Changes in the way your heart beats

Over breathing (hyperventilation)

Rare: (may affect up to 1 in 1000 people)

Fits (seizures)

Seizures have occurred after naloxone hydrochloride, but it is not known if these were caused by the drug.

Very Rare: (may affect up to 1 in 10000 people)

Heart attack (cardiac arrest)
Fluid in the lungs

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 IMB Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.imb.ie; e-mail: imbpharmacovigilance@imb.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Naloxone Hydrochloride

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, ampoule or blister pack label.

Do not store above 25°C.

Keep the ampoule or blister pack in the outer carton in order to protect from light.

6. Contents of the pack and other information

What Naloxone Hydrochloride contains

The active substance is naloxone hydrochloride. Each 2ml ampoule contains 40 micrograms of naloxone hydrochloride, present as naloxone hydrochloride dihydrate. The other ingredients are water and sodium chloride.

What Naloxone Hydrochloride looks like and contents of the pack

Naloxone Hydrochloride is a clear, colourless solution, packaged in clear Type I glass ampoules (small bottles) containing 2 ml of solution.

These are packaged in cartons containing 5 ampoules, blister packed in perforated strips.

Marketing Authorisation Holder & Manufacturer:

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Queensway
Royal Leamington Spa
Warwickshire CV31 3RW
United Kingdom

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