

DBL™ Naloxone Hydrochloride Injection

Naloxone Hydrochloride (nal-OX-own)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about DBL™ Naloxone Hydrochloride Injection (naloxone).

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor or pharmacist has weighed the risks of you being given DBL™ Naloxone Hydrochloride Injection against the benefits they expect it will have for you.

If you have any concerns about being given this medicine, ask your doctor or pharmacist.

Keep this leaflet in a safe place. You may need to read it again.

What DBL™ Naloxone Hydrochloride Injection is used for

Naloxone is a medicine which, when injected, reverses the effect of opium-like substances such as morphine, heroin and codeine.

It acts very quickly, within one or two minutes when injected into a vein, and can be a lifesaving measure in those people who have received an overdose of an opioid-like drug.

It may also be used after surgical operations when powerful pain killers which have been given

during the operation are no longer required.

Your doctor may have prescribed naloxone for another reason. Ask your doctor if you have any questions about why naloxone has been prescribed for you.

DBL™ Naloxone Hydrochloride Injection is not addictive.

This medicine is available only with a doctor's prescription.

Before you are given DBL™ Naloxone Hydrochloride Injection

When you must not be given it

You must not be given DBL™ Naloxone Hydrochloride Injection if you have an allergy to naloxone or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction to naloxone may include:

- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

If you are not sure whether you should be given DBL™ Naloxone Hydrochloride Injection, talk to your doctor or pharmacist.

Before you are given it

Tell your doctor or pharmacist if you have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes.

Tell your doctor or pharmacist if you are pregnant or intend to become pregnant.

Your doctor or pharmacist will discuss the possible risks and benefits of using DBL™ Naloxone Hydrochloride Injection during pregnancy.

Tell your doctor or pharmacist if you are breast-feeding or plan to breast-feed.

Your doctor or pharmacist will discuss the possible risks and benefits of using DBL™ Naloxone Hydrochloride Injection during breast-feeding. It is not known whether it passes into breast milk.

Tell your doctor or pharmacist if you have or have had any medical conditions, especially the following:

- heart disease
- lung disease
- drug addiction
- kidney disease
- liver disease.

If you have not told your doctor or pharmacist about any of the above, tell them before you are given DBL™ Naloxone Hydrochloride Injection.

Taking other medicines

Tell your doctor or pharmacist if you are taking or using any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and naloxone may interfere with each other. These include:

- pain killers
- cough and cold remedies
- heart or blood pressure medication.

These medicines may be affected by naloxone or may affect how well it works. You may need different amounts of your medicine or you may need to take or use different medicines. Your doctor or pharmacist will advise you.

Your doctor and pharmacist may have more information on medicines to be careful with or avoid while being given naloxone.

How DBL™ Naloxone Hydrochloride Injection is given

How much is given

Your doctor will decide what dose you will receive. This depends on your condition and other factors. It is usually given as a single dose but may be repeated if necessary.

How it is given

DBL™ Naloxone Hydrochloride Injection is given either:

- as an injection into a muscle (intramuscular),
- just under the skin (subcutaneous) or
- as a slow injection into a vein (intravenous). Injection into a vein is the most common site in an emergency.

DBL™ Naloxone Hydrochloride Injection should only be given by a doctor or nurse. In emergency situations it may be given by paramedical staff, such as an ambulance attendant.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much DBL™ Naloxone Hydrochloride Injection. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

DBL™ Naloxone Hydrochloride Injection is known to be safe in very large doses in animals. However, severe withdrawal symptoms can be produced in drug addicts if too much naloxone is used. Ask your doctor or pharmacist if you have any concerns.

While you are being given DBL™ Naloxone Hydrochloride Injection

Things to be careful of

Be careful driving or operating machinery until you know how DBL™ Naloxone Hydrochloride Injection affects you.

Be careful when drinking alcohol while you are taking this medicine.

This medicine may cause light-headedness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.

Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are being given DBL™ Naloxone Hydrochloride Injection.

Naloxone helps most people but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by the following list of side effects.

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Abrupt reversal of the effects of opium-like substances may result in withdrawal symptoms.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- nausea or vomiting
- sweating
- increased heart rate
- tremor
- rapid breathing
- light-headedness or dizziness
- nervousness or restlessness
- irritability or excitement.
- violent behaviour or agitation
- tingling in the hands or feet

These are the more common side effects of naloxone. Mostly these are mild and short-lived.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After you have been given DBL™ Naloxone Hydrochloride Injection

Storage

DBL™ Naloxone Hydrochloride Injection will be stored in the pharmacy or on the ward. The injection is kept in a cool dry place, protected from light, where the temperature stays below 25°C.

Disposal

DBL™ Naloxone Hydrochloride Injection will be disposed of by a health care professional.

Product description

What it looks like

DBL™ Naloxone Hydrochloride Injection is a clear colourless solution. It should not be given if there are any crystals or particles visible in the solution.

Ingredients

Active ingredient:

- naloxone hydrochloride

Other ingredients:

- sodium chloride
- water for Injections.

DBL™ Naloxone Hydrochloride Injection does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Supplier / Sponsor

DBL™ Naloxone Hydrochloride is supplied by:

Australian Sponsor:

Hospira Australia Pty Ltd
ABN 58 097 064 330
Level 3
500 Collins Street
Melbourne VIC 3000
Australia

New Zealand Sponsor:

Hospira NZ Limited
58 Richard Pearse Drive
Airport Oaks, Mangere, 2022
Auckland
New Zealand

DBL™ Naloxone Hydrochloride Injection is available in the following strengths and packs:

- 400 microgram/mL, 5 x 1mL
AUST R 16282

This leaflet was updated in June 2016.