

DBL™ Naloxone Hydrochloride

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I being given DBL Naloxone Hydrochloride?

DBL Naloxone Hydrochloride contains the active ingredient naloxone hydrochloride dihydrate. Naloxone is used to reverse the effects of opium-like substances for example, morphine, heroin, methadone or codeine.

For more information, see Section [1. Why am I being treated with DBL Naloxone Hydrochloride?](#) in the full CMI.

2. What should I know before I am given DBL Naloxone Hydrochloride?

Do not start treatment if you have ever had an allergic reaction to naloxone or any of the ingredients listed at the end of this CMI.

Talk to your doctor if you have an addiction to, or regularly use opioids (including babies of mothers who fall into this category); have heart, lung, kidney or liver disease, or any other medical conditions; take any other medicines; or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before treatment with DBL Naloxone Hydrochloride?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines, including some pain medicines and cold and cough medicines, may interfere with DBL Naloxone Hydrochloride and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How is DBL Naloxone Hydrochloride given?

DBL Naloxone Hydrochloride is given as an injection into a muscle, under the skin or as a slow injection into a vein.

Your dose depends on whether you are an adult, child or baby and how you are receiving DBL Naloxone Hydrochloride.

More instructions can be found in Section [4. How is DBL Naloxone Hydrochloride given?](#) in the full CMI.

5. What should I know while I am being given DBL Naloxone Hydrochloride?

Things you should do	<ul style="list-style-type: none">Remind any doctor, nurse, pharmacist or dentist you visit that you are being given this medicine.Tell your doctor if you are pregnant, intend to become pregnant or are breastfeeding.Tell your doctor if you have heart, lung, kidney or liver disease, or drug addiction.If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly after being given DBL Naloxone Hydrochloride.
Driving or using machines	<ul style="list-style-type: none">Be careful driving or using any machines or tools until you know how this medicine affects you.
Drinking alcohol	<ul style="list-style-type: none">Be careful when drinking alcohol while you are being given this medicine.
Looking after your medicine	<ul style="list-style-type: none">DBL Naloxone Hydrochloride will usually be stored in the pharmacy or on the ward.If you need to store this medicine, keep it in a cool, dry, dark place, below 25°C.

For more information, see Section [5. What should I know during treatment with DBL Naloxone Hydrochloride?](#) in the full CMI.

6. Are there any side effects?

Symptoms of opioid withdrawal if you or your baby are dependent on opioids.

Side-effects not specific to opioid withdrawal may include: nausea/vomiting; sweating; agitation; headache; light-headedness, dizziness; hyperventilating; tremors; seizures/fits; fast or abnormal heartbeat; coughing up bloody or frothy mucus; coma; heart suddenly stops beating which may lead to death.

Allergic reaction, which may be serious. Symptoms may include: shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body, and rash, itching or hives on the skin.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

DBL™ Naloxone Hydrochloride

Active ingredient(s): naloxone hydrochloride dihydrate

Consumer Medicine Information (CMI)

This leaflet provides important information about using DBL Naloxone Hydrochloride.

You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using DBL Naloxone Hydrochloride.

Where to find information in this leaflet:

1. [Why am I being given DBL Naloxone Hydrochloride?](#)
2. [What should I know before I am given DBL Naloxone Hydrochloride?](#)
3. [What if I am taking other medicines?](#)
4. [How is DBL Naloxone Hydrochloride given?](#)
5. [What should I know while I am being given DBL Naloxone Hydrochloride?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I being given DBL Naloxone Hydrochloride?

DBL Naloxone Hydrochloride contains the active ingredient naloxone hydrochloride dihydrate.

It belongs to a group of medicines known as opioid antagonists.

DBL Naloxone Hydrochloride is used to reverse the effects of opium-like substances such as morphine, heroin, methadone or codeine.

It may also be used after surgical operations when powerful pain killers which have been given during the operation are no longer required.

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

DBL Naloxone Hydrochloride is not addictive.

2. What should I know before I am given DBL Naloxone Hydrochloride?

Warnings

You must not be given DBL Naloxone Hydrochloride if:

1. you are allergic to naloxone or any of the ingredients listed at the end of this leaflet.
Symptoms of an allergic reaction 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.

Check with your doctor if you:

Have or have had any other medical conditions, especially the following:

- heart disease
- lung disease
- kidney disease
- liver disease
- drug addiction (including babies born to mothers with opioid addiction or regular opioid use)

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

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

Naloxone crosses the placenta and can be absorbed by the unborn baby. This may result in withdrawal symptoms in the baby as well as the mother, if the mother has regularly taken opioids over the course of her pregnancy.

Your doctor or pharmacist will discuss the risks and benefits of being given naloxone during pregnancy.

Talk to your doctor or pharmacist if you are breastfeeding or intend to breastfeed.

It is not known whether naloxone passes into breast milk.

Your doctor or pharmacist will discuss the possible risks and benefits of being given naloxone when breast-feeding.

If you have not told your doctor about any of the above, tell them before you are given this medicine.

3. What if I am taking other medicines?

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

Some medicines may interfere with DBL Naloxone Hydrochloride and affect how it works. These include:

- Pain killers (e.g. codeine, buprenorphine or pentazocine)
- Cough and cold remedies
- Heart and blood pressure medication.

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

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect DBL Naloxone Hydrochloride.

4. How is DBL Naloxone Hydrochloride given?

How much is given

For a known or suspected overdose in an adult, an initial dose of 1 to 5 ampoules of DBL Naloxone Hydrochloride may be used. This may be repeated at 2 to 3 minute intervals, up to a total of 25 DBL Naloxone Hydrochloride ampoules being used.

For a known or suspected overdose in a child, medical advice must be obtained to determine how much is given.

Seek emergency services if delivered outside a hospital setting.

In hospital settings, your doctor will decide what dose you will receive and how often.

How it is given

DBL Naloxone Hydrochloride may be given either:

- as an injection into a muscle (intramuscular)
- just under your skin (subcutaneous) or
- as a slow injection into a vein (intravenous).

Injection into a vein is the most common site in an emergency.

If you are given too much DBL Naloxone Hydrochloride

Symptoms of an overdose include the side effects listed below in [Section 6. Are there any side effects?](#) but are usually of a more severe nature.

If you think that too much DBL Naloxone Hydrochloride has been given and/or if you experience severe side effects, you should immediately:

- contact your doctor, or
- phone the Poisons Information Centre (by calling 13 11 26), or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Severe withdrawal symptoms can be produced in patients who are regular users of opioids (or babies born to women who are regularly take opioids) if too much naloxone is used.

Ask your doctor or pharmacist if you have any concerns.

5. What should I know while I am being given DBL Naloxone Hydrochloride?

Things you should do

Remind any doctor, nurse, pharmacist or dentist you visit that you are receiving DBL Naloxone Hydrochloride.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are receiving this medicine.

If you become pregnant while receiving DBL Naloxone Hydrochloride, tell your doctor or pharmacist immediately.

Tell your doctor if you have heart disease, lung disease, kidney disease, liver disease or drug addiction.

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. If this problem continues or gets worse, talk to your doctor.

Driving or using machines

Be careful driving or using any machines or tools until you know how DBL Naloxone Hydrochloride affects you.

Drinking alcohol

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

Looking after your medicine

DBL Naloxone Hydrochloride will usually be stored in the pharmacy or on the ward.

However, if you need to store DBL Naloxone Hydrochloride, it should be kept in a cool dry place, protected from light by keeping the ampoules in the box, and where the temperature stays below 25°C.

For example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Abrupt reversal of the effects of opium-like substances may result in withdrawal symptoms, which can be serious.

Side effect	What to do
The symptoms of opioid withdrawal that may be experienced if you or your baby	Tell your doctor or nurse or go immediately to Accident and

Side effect	What to do
<p>are dependent on opioids may include:</p> <ul style="list-style-type: none"> body aches diarrhoea, stomach cramps fast heartbeat fever runny nose, sneezing goose pimples, sweating, shivering tremors yawning nausea or vomiting nervousness, restlessness irritability, abnormal excitability or violent behaviours tingling, numbness, pins and needles weakness headache seizures/fits. <p>Additional symptoms in babies may include:</p> <ul style="list-style-type: none"> excessive crying abnormal movements. <p>General side effects not specific to opioid withdrawal may include:</p> <ul style="list-style-type: none"> nausea or vomiting sweating agitation headache light-headedness, dizziness hyperventilating tremors coughing up bloody or frothy mucus fast or abnormal heartbeat seizures/fits coma heart suddenly stops beating which may lead to death. 	<p>Emergency if you notice any of the following during treatment with DBL Naloxone Hydrochloride.</p> <p>You may need urgent medical attention.</p>
<p>Symptoms of an allergic reaction may include:</p> <ul style="list-style-type: none"> shortness of breath wheezing or difficulty breathing swelling of the face, lips, tongue or other parts of the body rash, itching or hives in the skin. 	<p>Tell your doctor or nurse immediately if you notice any of the following</p> <p>These may be more serious side effects. You may need urgent medical attention.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/safety/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop treatment with any of your medicines.

7. Product details

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

What DBL Naloxone Hydrochloride contains

Active ingredient (main ingredient)	Naloxone hydrochloride dihydrate
Other ingredients (inactive ingredients)	Hydrochloric acid Sodium Chloride Water for Injections

Do not use this medicine if you are allergic to any of these ingredients.

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

What DBL Naloxone Hydrochloride looks like

DBL Naloxone Hydrochloride is a clear, colourless solution.

It should not be given if there are any crystals or particles visible in the solution.

DBL Naloxone Hydrochloride is available as follows:

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

Who distributes DBL Naloxone Hydrochloride

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

www.pfizermedicalinformation.com.au

This leaflet was prepared in September 2025.

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