

DBL™ SODIUM NITROPRUSSIDE CONCENTRATED INJECTION

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 Sodium Nitroprusside Concentrated Injection?

DBL Sodium Nitroprusside Concentrated Injection contains the active ingredient sodium nitroprusside dihydrate. DBL Sodium Nitroprusside Concentrated Injection is used in emergency situations to quickly lower very high blood pressure (also known as hypertensive crisis). It can also be used to keep blood pressure low in order to reduce bleeding during surgical procedures and in the short-term treatment of heart failure.

For more information, see Section [1. Why am I being given DBL Sodium Nitroprusside Concentrated Injection?](#) in the full CMI.

2. What should I know before I am given DBL Sodium Nitroprusside Concentrated Injection?

You will not be given DBL Sodium Nitroprusside Concentrated Injection if you have ever had an allergic reaction to sodium nitroprusside or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any heart problems 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 I am given DBL Sodium Nitroprusside Concentrated Injection?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with DBL Sodium Nitroprusside Concentrated Injection 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 Sodium Nitroprusside Concentrated Injection given?

DBL Sodium Nitroprusside Concentrated Injection is given by slow injection (drip) into a vein. It must only be given by a doctor or nurse. Your doctor will decide what dose, how often, and how long you will receive it.

More instructions can be found in Section [4. How is DBL Sodium Nitroprusside Concentrated Injection given?](#) in the full CMI.

5. What should I know while being given DBL Sodium Nitroprusside Concentrated Injection?

Things you should do	<ul style="list-style-type: none">Remind any doctor, dentist, nurse or pharmacist you visit that you are receiving DBL Sodium Nitroprusside Concentrated Injection.If you become pregnant, while taking this medicine, tell your doctor immediately.
Driving or using machines	<ul style="list-style-type: none">Be careful driving or operating machinery until you know how this medicine affects you. If you have symptoms of dizziness or drowsiness, do not drive, operate machinery or do anything else that could be dangerous.

For more information, see Section [5. What should I know while being given DBL Sodium Nitroprusside Concentrated Injection?](#) in the full CMI.

6. Are there any side effects?

Side effects may include: nausea and vomiting, sweating, apprehension, restlessness, headache, muscle twitching, dizziness, drowsiness, 'pins and needles', abdominal pain, skin rash, blockage in the bowel and redness at the injection site.

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™ SODIUM NITROPRUSSIDE CONCENTRATED INJECTION

Active ingredient: *sodium nitroprusside*

Consumer Medicine Information (CMI)

This leaflet provides important information about using DBL Sodium Nitroprusside Concentrated Injection. **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 Sodium Nitroprusside Concentrated Injection.**

Where to find information in this leaflet:

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

1. Why am I being given DBL Sodium Nitroprusside Concentrated Injection?

DBL Sodium Nitroprusside Concentrated Injection contains the active ingredient sodium nitroprusside dihydrate. Sodium nitroprusside is known as a vasodilator. It works by widening blood vessels, which causes a decrease in blood pressure.

DBL Sodium Nitroprusside Concentrated Injection is used:

- in emergency situations to quickly lower very high blood pressure (also known as hypertensive crisis)
- during surgery to keep blood pressure low in order to reduce bleeding during surgical procedures
- in the short-term treatment of heart failure.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

There is no evidence that sodium nitroprusside is addictive.

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

2. What should I know before I am given DBL Sodium Nitroprusside Concentrated Injection?

Warnings

You should not be given DBL Sodium Nitroprusside Concentrated Injection if:

- you are allergic to sodium nitroprusside 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
- you have untreated anaemia (reduced red blood cells and iron stores)
- you have inadequate blood supply to the brain
- you have low blood volume (hypovolaemia)
- you have acute congestive heart failure
- you have severe kidney disease
- you have any disease states associated with Vitamin B12 deficiency
- you have some rare conditions causing reduced vision such as Leber's optic atrophy and tobacco amblyopia.

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

- raised intracranial pressure (raised pressure within the head)
- thyroid problems
- kidney disease
- liver disease
- high blood pressure
- hypothermia (decreased body temperature).

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.

DBL Sodium Nitroprusside Concentrated Injection is not recommended for use during pregnancy. Your doctor will discuss with you the risks and benefits involved.

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

DBL Sodium Nitroprusside Concentrated Injection is not recommended while you breastfeeding as it not known whether DBL Sodium Nitroprusside Concentrated Injection passes into breast milk.

If you have not told your doctor or pharmacist about any of the above, tell them before you are given DBL Sodium Nitroprusside Concentrated Injection.

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 and DBL Sodium Nitroprusside Concentrated Injection may interfere with each other.

These include:

- blood pressure medications
- some anaesthetics
- some heart medications.

These medicines may be affected by DBL Sodium Nitroprusside Concentrated Injection 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 Sodium Nitroprusside Concentrated Injection.

4. How is DBL Sodium Nitroprusside Concentrated Injection given?

Your treatment with DBL Sodium Nitroprusside Concentrated Injection will be under the supervision of a doctor. This medicine will be given by a healthcare professional (e.g. doctor or nurse) experienced in giving this type of medicine.

How much is given

- Your doctor will decide what dose of DBL Sodium Nitroprusside Concentrated Injection you will receive. This depends on your condition and other factors, such as your weight.

How it is given

- DBL Sodium Nitroprusside is given by slow injection (drip) into a vein.

If too much DBL Sodium Nitroprusside Concentrated Injection is given

DBL Sodium Nitroprusside Concentrated Injection is given in a hospital or clinic under the supervision of a doctor, it is very unlikely that you will be given too much of the medicine. Your doctor or nurse will be monitoring your progress and checking the medicine that you are given.

If you think that you have been given too much DBL Sodium Nitroprusside Concentrated Injection, you may need urgent medical attention.

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

5. What should I know while being given DBL Sodium Nitroprusside Concentrated Injection?

Things you should do

Tell your doctor if you become pregnant during treatment with this medicine.

Remind any doctor, dentist, nurse or pharmacist you visit that you are using DBL Sodium Nitroprusside Concentrated Injection.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how DBL Sodium Nitroprusside Concentrated Injection affects you.

DBL Sodium Nitroprusside Concentrated Injection may cause dizziness and drowsiness in some people.

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.

If you are over 65 years of age, you may have an increased chance of getting side effects. **Do not be alarmed by this list of possible side effects.** You may not experience any of them.

Side effects

Side effects	What to do
<p>General disorders</p> <ul style="list-style-type: none"> • sweating • apprehension, restlessness • muscle twitching • dizziness, drowsiness • 'pins and needles' <p>Gastrointestinal System disorders:</p> <ul style="list-style-type: none"> • nausea and vomiting • abdominal pain • blockage in the bowel <p>Administrative site conditions</p> <ul style="list-style-type: none"> • skin rash • redness at the injection site 	<p>Speak to your doctor if you have any of these side effects and they worry you.</p>

These are the more common side effects of DBL Sodium Nitroprusside Concentrated Injection. Mostly these are mild and short-lived.

Serious side effects

Serious side effects	What to do
<p>General disorders:</p> <ul style="list-style-type: none"> headache (raised intracranial pressure) lack of oxygen (due to methemoglobinemia, a condition which reduces the blood's ability to carry oxygen) <p>Vascular disorders:</p> <ul style="list-style-type: none"> fainting due to very low blood pressure <p>Blood and lymphatic system disorders:</p> <ul style="list-style-type: none"> signs of bleeding or bruising <p>Cardiac disorders:</p> <ul style="list-style-type: none"> changes in heart rate very low blood pressure <p>Hormonal disorders:</p> <ul style="list-style-type: none"> symptoms of hypothyroidism such as weight gain, lethargy, dryness of the skin, constipation <p>Signs of toxicity</p> <ul style="list-style-type: none"> signs of cyanide toxicity. These include: confusion, air hunger (trouble breathing), angina, seizures signs of thiocyanate toxicity. These include: ringing in the ears, constricted pupils and hyperreflexia (enhanced reflexes) 	<p>Call your doctor straight away if you notice any of these serious side effects.</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/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 taking any of your medicines.

7. Product details

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

What DBL Sodium Nitroprusside Concentrated Injection contains

Active ingredient (main ingredient)	sodium nitroprusside dihydrate
Other ingredients (inactive ingredients)	sterile water for injection

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

DBL Sodium Nitroprusside Concentrated Injection does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

What DBL Sodium Nitroprusside Concentrated Injection looks like

DBL Sodium Nitroprusside Concentrated Injection is a clear solution available in amber glass vials containing the equivalent of 50 mg sodium nitroprusside dihydrate in 2 mL solution.

Australian Registration Number

DBL Sodium Nitroprusside Concentrated Injection
50mg/2mL vial - AUST R 177111

Who distributes DBL Sodium Nitroprusside Concentrated Injection

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

www.pfizermedicalinformation.com.au

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