

DBL™ SODIUM NITROPRUSSIDE CONCENTRATED INJECTION

Sodium nitroprusside (Sodium Nitro-PRUSS-ide)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about DBL™ Sodium Nitroprusside Concentrated Injection.

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 has weighed the risks of you being given this medicine 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 with the medicine.

You may need to read it again.

What DBL™ Sodium Nitroprusside Concentrated Injection is used for

Sodium nitroprusside is known as a vasodilator. It works by widening blood vessels, which causes a decrease in blood pressure.

Sodium nitroprusside is used in emergency situations to quickly lower very high blood pressure (also known as hypertensive crisis).

It can also be used during surgery to keep blood pressure low in order to reduce bleeding during the surgical procedure. It may also be used in the short-term treatment of heart failure.

Your doctor may have prescribed DBL™ Sodium Nitroprusside Concentrated Injection for another reason.

Ask your doctor if you have any questions about why DBL™ Sodium Nitroprusside Concentrated Injection has been prescribed for you.

Sodium nitroprusside is not addictive.

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

Before you are given DBL™ Sodium Nitroprusside Concentrated Injection

When you must not be given it

You must not be given DBL™ Sodium Nitroprusside Concentrated Injection if you have an allergy to sodium nitroprusside or cyanide.

Symptoms of an allergic reaction to sodium nitroprusside 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 must not be given sodium nitroprusside if you have or have had any of the following medical conditions:

- untreated anaemia (reduced red blood cells and iron stores)
- inadequate blood supply to the brain
- low blood volume (hypovolaemia)
- acute congestive heart failure
- severe kidney disease
- any disease states associated with Vitamin B12 deficiency

- some rare conditions causing reduced vision such as Leber's optic atrophy and tobacco amblyopia.

If you are not sure whether you should be given DBL™ Sodium Nitroprusside Concentrated 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 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).

Tell your doctor or pharmacist if you are pregnant.

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

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

DBL™ Sodium Nitroprusside Concentrated Injection is not recommended while you are breast-feeding as it is 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.

Taking other medicines

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

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

- ganglion blocking agents
- blood pressure medications
- some anaesthetics
- some heart medications.

These medicines may be affected by sodium nitroprusside 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.

How DBL™ Sodium Nitroprusside Concentrated Injection is given

How much is given

Your doctor will decide what dose of sodium nitroprusside you will receive. This depends on your condition and other factors, such as your weight.

How it is given

DBL™ Sodium Nitroprusside Concentrated Injection is given as a slow infusion (or 'drip') into a vein (intravenously). DBL™ Sodium Nitroprusside Concentrated Injection must only be given by a doctor or nurse.

Overdose

As sodium nitroprusside is given to you under the supervision of your doctor, it is very unlikely that you will receive too much. However, if you experience any severe side effects after being given sodium nitroprusside, tell your doctor immediately, phone the Poisons Information Centre (telephone 13 11 26 in Australia, or call 0800 764 766 in New Zealand) for advice, or go to Accident and Emergency at the nearest hospital. You may need urgent medical attention.

Symptoms of a sodium nitroprusside overdose include the side effects listed below in the 'Side Effects' section, but are usually of a more severe nature.

Side effects

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

Sodium nitroprusside 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.

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

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.

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

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

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

If any of the following happen, tell your doctor or nurse immediately:

- signs of cyanide toxicity. These include confusion, air hunger (trouble breathing), angina, seizures
- fainting due to very low blood pressure
- lack of oxygen (due to methemoglobinemia, a condition which reduces the blood's ability to carry oxygen)

- signs of thiocyanate toxicity, such as ringing in the ears, constricted pupils and hyperreflexia (enhanced reflexes)
- changes in heart rate
- symptoms of hypothyroidism such as weight gain, lethargy, dryness of the skin, constipation
- signs of bleeding or bruising
- headache (raised intracranial pressure).

These are serious side effects. You may need urgent medical attention.

Other side effects not listed above may occur in some patients.

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

After you have been given DBL™ Sodium Nitroprusside Concentrated Injection

Storage

DBL™ Sodium Nitroprusside Concentrated 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.

In aqueous solution, it is photosensitive and must be protected from light.

Product description

What it 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.

Ingredients

Active ingredient:

- sodium nitroprusside dihydrate

Other ingredients:

- sterile water for injection

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

Sponsor

Australian Sponsor

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free number: 1800 675 229

www.pfizer.com.au

New Zealand Sponsor

Pfizer New Zealand Ltd

PO Box 3998

Auckland, New Zealand

Toll Free number: 0800 736 363

DBL™ Sodium Nitroprusside Concentrated Injection is available in the following strength:

- 50mg/ 2mL vial AUST R 177111

This leaflet was updated in: September 2019