SODIUM NITROPRUSSIDE BAXTER

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 using SODIUM NITROPRUSSIDE BAXTER?

SODIUM NITROPRUSSIDE BAXTER contains the active ingredient Sodium nitroprusside. SODIUM NITROPRUSSIDE BAXTER is used for;

- Immediate reduction of blood pressure in patients with hypertensive crises
- Producing controlled hypotension during anaesthesia in order to reduce bleeding in surgical procedures
- Short term therapy of cardiac failure, to enhance cardiac output and lower myocardial oxygen requirements

For more information, see Section 1. Why am I using SODIUM NITROPRUSSIDE BAXTER? in the full CMI.

2. What should I know before I use SODIUM NITROPRUSSIDE BAXTER?

Do not use if you have ever had an allergic reaction to SODIUM NITROPRUSSIDE BAXTER or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have 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 use SODIUM NITROPRUSSIDE BAXTER? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with SODIUM NITROPRUSSIDE BAXTER 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 do I use SODIUM NITROPRUSSIDE BAXTER?

- SODIUM NITROPRUSSIDE BAXTER should only be used as an infusion with sterile 5% Glucose in water. It should not be administered by direct injection.
- This medicinal product must not be mixed with other medicinal products. SODIUM NITROPRUSSIDE BAXTER is for single use in one patient only. Discard any residue.

More instructions can be found in Section 4. How do I use SODIUM NITROPRUSSIDE BAXTER? in the full CMI.

5. What should I know while using SODIUM NITROPRUSSIDE BAXTER?

Things you should do	Tell your doctor if you experience any problems with this medicine.
Driving or using machines	No specific studies have been conducted to assess the direct effect of sodium nitroprusside on the ability to drive and use machines. However, adverse effects of sodium nitroprusside include dizziness and drowsiness which could affect the ability to drive or use machines.
Looking after your medicine	 Keep out of the reach and sight of children. Store below 25°C. Protect from light. Retain in carton until time of use.

For more information, see Section 5. What should I know while using SODIUM NITROPRUSSIDE BAXTER? in the full CMI.

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.

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.

SODIUM NITROPRUSSIDE BAXTER

Active ingredient(s): Sodium nitroprusside

Consumer Medicine Information (CMI)

This leaflet provides important information about using SODIUM NITROPRUSSIDE BAXTER. 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 SODIUM NITROPRUSSIDE BAXTER.

Where to find information in this leaflet:

- 1. Why am I using SODIUM NITROPRUSSIDE BAXTER?
- 2. What should I know before I use SODIUM NITROPRUSSIDE BAXTER?
- 3. What if I am taking other medicines?
- 4. How do I use SODIUM NITROPRUSSIDE BAXTER?
- 5. What should I know while using SODIUM NITROPRUSSIDE BAXTER?
- 6. Are there any side effects?
- 7. Product details

1. Why am I using SODIUM NITROPRUSSIDE BAXTER?

SODIUM NITROPRUSSIDE BAXTER contains the active ingredient Sodium nitroprusside. Sodium nitroprusside is a direct acting vasodilator used to treat hypertension, to induce controlled hypotension to reduce postoperative bleeding and to manage acute heart failure.

SODIUM NITROPRUSSIDE BAXTER is indicated for:

- Immediate reduction of blood pressure in patients with hypertensive crises. Concomitant oral antihypertensive medication should be started while the hypertensive emergency is being brought under control with sodium nitroprusside.
- Producing controlled hypotension during anaesthesia in order to reduce bleeding in surgical procedures where surgeon and anaesthetist deem it appropriate.
- Short term therapy of cardiac failure, to enhance cardiac output and lower myocardial oxygen requirements. Patients should be commenced on oral therapy as soon as possible.

2. What should I know before I use SODIUM NITROPRUSSIDE BAXTER?

Warnings

Do not use SODIUM NITROPRUSSIDE BAXTER if:

- you are allergic to Sodium nitroprusside or cyanide.
- Sodium nitroprusside should not be used in the treatment of compensatory hypertension.
- Sodium nitroprusside should not be used in physically poor risk patients with known inadequate cerebral circulation or in moribund patients

- You have some rare conditions causing reduced vision such as Leber's optic atrophy and tobacco amblyopia
- Sodium nitroprusside should be used for treatment of acute congestive heart failure
- Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have any other medical conditions
- take any medicines for any other condition

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?

Fertility, pregnancy and breastfeeding

Sodium nitroprusside has not been tested for effects on fertility.

Sodium nitroprusside should be given to a pregnant woman only if clearly needed. Your doctors will discuss with you the risks and benefits involved.

Sodium nitroprusside is not recommended while you are breastfeeding as it is not known whether Sodium nitroprusside passes into breast milk.

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

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 sodium nitroprusside may interfere with each other. These include:

- Ganglion blocking agents
- Blood pressure medications
- Some anaesthetics
- Some heart medications

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect SODIUM NITROPRUSSIDE BAXTER.

4. How do I use SODIUM NITROPRUSSIDE BAXTER?

How much to use

- Sodium nitroprusside is given as a slow infusion (or "drip") into a vein (intravenously)
- Your doctor will decide how much of this medicine you will be given and for how long.
- SODIUM NITROPRUSSIDE is only to be used as an infusion with sterile 5% glucose in water. It should not be administered by direct injection.
- Depending on the desired concentration, SODIUM NITROPRUSSIDE BAXTER concentrated injection containing 50 mg/2 mL sodium nitroprusside must be further diluted in 500-1000 mL of sterile 5% glucose injection.
- If you have any further questions on the use of this medicine, ask your doctor, pharmacist, or nurse.
- No other drugs should be administered in the same solution with Sodium nitroprusside

If you forget to use SODIUM NITROPRUSSIDE BAXTER

If you miss a dose of SODIUM NITROPRUSSID EBAXTER, you should be given the dose as soon as possible. Your doctor will adjust your dosing schedule to ensure the appropriate time between doses.

If you use too much SODIUM NITROPRUSSIDE BAXTER

As this medicine 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 side effects after being given it, tell your doctor immediately.

If you think that you have used too much SODIUM NITROPRUSSIDE BAXTER, you may need urgent medical attention.

You should immediately:

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

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

5. What should I know while using SODIUM NITROPRUSSIDE BAXTER?

Things you should do

If the medicine starts to upset you or your symptoms become worse, tell your doctor. Tell your doctor if you become pregnant during treatment with this medicine.

Remind any doctor, dentist or pharmacist you visit that you are using SODIUM NITROPRUSSIDE BAXTER.

Driving or using machines

No specific studies have been conducted to assess the direct effect of sodium nitroprusside on the ability to drive and use machines. However, adverse effects of sodium nitroprusside include dizziness and drowsiness which could affect the ability to drive or use machines

Looking after your medicine

- · Keep out of the reach and sight of children.
- Store below 25°C.
- Protect from light.
- · Retain in carton until time of use.
- In aqueous solution, it is photosensitive and must be protected from light.

When to discard your medicine

Do not use this medicine if the expiry date printed on the pack has passed.

Getting rid of any unwanted medicine

Your doctor, nurse or pharmacist will dispose of any leftover medicine.

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.

Common side effects

Common effects	What to do
The following common side effects may occur. 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	Speak to your doctor if you have any of these common side effects and they worry you.

Uncommon side effects

Uncommon side effects	What to do
The following uncommon side effects may also occur. 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 (raise intracranial pressure)	Speak to your doctor if you have any of these uncommon side effects and they worry you.

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 SODIUM NITROPRUSSIDE BAXTER contains

Active ingredient (main ingredient)	Sodium nitroprusside dihydrate [sodium nitrosylpentacyanoferrate (III)]
Other ingredients	Water for injection
(inactive ingredients)	

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

What SODIUM NITROPRUSSIDE BAXTER looks like

SODIUM NITROPRUSSIDE BAXTER concentration injection is a clear, reddish brown colour solution.

SODIUM NITROPRUSSIDE BAXTER concentration injection is available in amber glass vials containing the equivalent of 50mg sodium nitroprusside dihydrate in 2 mL solution.

SODIUM NITROPRUSSIDE BAXTER Registration Number: 391482

Who distributes SODIUM NITROPRUSSIDE BAXTER

Baxter Healthcare Pty Ltd 1 Baxter Drive OLD TOONGABBIE NSW 2146 AUSTRALIA

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