NITROPRUSSIDE SXP

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 NITROPRUSSIDE SXP?

NITROPRUSSIDE SXP Concentrated Injection contains the active ingredient sodium nitroprusside. NITROPRUSSIDE SXP is used to quickly lower very high blood pressure.

For more information, see Section 1. Why am I am given NITROPRUSSIDE SXP? in the full CMI.

2. What should I know before I am given NITROPRUSSIDE SXP?

Do not use 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 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 NITROPRUSSIDE SXP? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with NITROPRUSSIDE SXP 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 am I given NITROPRUSSIDE SXP?

Your doctor will decide what dose of NITROPRUSSIDE SXP you will receive. This depends on your condition and other factors such as your weight. NITROPRUSSIDE SXP is given as a slow infusion (or 'drip') into a vein by a doctor or nurse.

More instructions can be found in Section 4. How am I given NITROPRUSSIDE SXP? in the full CMI.

5. What should I know while being given NITROPRUSSIDE SXP?

Things you should do	Remind any doctor, dentist or pharmacist you visit that you are being given NITROPRUSSIDE SXP.
Things you should not do	You must not be given Nitroprusside SXP if you have an allergy to sodium nitroprusside or cyanide.
Driving or using machines	Sodium nitroprusside may cause dizziness and drowsiness in some people, which could affect the ability to drive or use machines.
Drinking alcohol	Tell your doctor if you drink alcohol.

For more information, see Section 5. What should I know while being given NITROPRUSSIDE SXP? in the full CMI.

6. Are there any side effects?

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.

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.

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.

NITROPRUSSIDE SXP

Active ingredient(s): Sodium nitroprusside (Sodium Nitro-PRUSS-ide)

Consumer Medicine Information (CMI)

This leaflet provides important information about using NITROPRUSSIDE SXP. 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 NITROPRUSSIDE SXP.

Where to find information in this leaflet:

- 1. Why am I being given NITROPRUSSIDE SXP?
- 2. What should I know before I am given NITROPRUSSIDE SXP?
- 3. What if I am taking other medicines?
- 4. How am I given NITROPRUSSIDE SXP?
- 5. What should I know while being given NITROPRUSSIDE SXP?
- 6. Are there any side effects?
- 7. Product details

1. Why am I being given NITROPRUSSIDE SXP?

NITROPRUSSIDE SXP contains the active ingredient sodium nitroprusside. NITROPRUSSIDE SXP is known as a vasodilator and works by widening the blood vessels, which causes a decrease in blood pressure.

NITROPRUSSIDE SXP 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.

NITROPRUSSIDE SXP may also be used in the short-term treatment of heart failure.

2. What should I know before I am given NITROPRUSSIDE SXP?

Warnings

You must not be given NITROPRUSSIDE SXP if you:

 are allergic to sodium nitroprusside, cyanide, or any of the ingredients listed at the end of this leaflet.
 Always check the ingredients to make sure you can use this medicine.

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.

- have untreated anaemia (reduced red blood cells and iron stores)
- have inadequate blood supply to the brain
- have low blood volume (hypovolaemia)
- have acute congestive heart failure

- have severe kidney disease
- have any disease states associated with Vitamin B12 deficiency
- have some rare conditions causing reduced vision such as Leber's optic atrophy and tobacco amblyopia.

Check with your doctor if you have or have had:

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

If you are not sure whether you should be given NITROPRUSSIDE SXP Injection, talk to your doctor or pharmacist.

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 if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed. NITROPRUSSIDE SXP passes into breast milk.

NITROPRUSSIDE SXP Injection is not recommended for use during pregnancy or breastfeeding.

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.

Tell your doctor or pharmacist if you have allergies to any medicines, or other substances such as preservatives or dyes.

Some medicines and NITROPRUSSIDE SXP 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 NITROPRUSSIDE SXP.

4. How am I given NITROPRUSSIDE SXP?

How NITROPRUSSIDE SXP 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.

When NITROPRUSSIDE SXP is given

NITROPRUSSIDE SXP Concentrated Injection is given as a slow infusion (or 'drip') into a vein (intravenously).

NITROPRUSSIDE SXP Concentrated Injection must only be given by a doctor or nurse.

NITROPRUSSIDE SXP 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.

If you are given too much NITROPRUSSIDE SXP

As NITROPRUSSIDE SXP is given to you under the supervision of your doctor, it is very unlikely that you will receive too much.

If you think that you have used too much NITROPRUSSIDE SXP or if you experience severe side effects, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- · contact your nurse or 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.

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

5. What should I know while being given NITROPRUSSIDE SXP?

Things you should do

Remind any doctor, dentist or pharmacist you visit that have been given NITROPRUSSIDE SXP.

Things you should not do

You must not be given Nitroprusside SXP if you have an allergy to sodium nitroprusside or cyanide.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how NITROPRUSSIDE SXP affects you.

NITROPRUSSIDE SXP may cause dizziness or drowsiness in some people, which could affect the ability to drive or use machines.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

NITROPRUSSIDE SXP 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 including during transport and storage.

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.

Less serious side effects

Less serious side effects		What to do
•	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 or nurse if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects		What to do
•	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)	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Tell your doctor or nurse 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 NITROPRUSSIDE SXP contains

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

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

NITROPRUSSIDE SXP is not addictive.

What NITROPRUSSIDE SXP looks like

NITROPRUSSIDE SXP is a clear reddish- brown solution containing 50 mg/ 2 mL of sodium nitroprusside dihydrate, presented in an amber vial (AUST R 381450).

Who distributes NITROPRUSSIDE SXP

Southern XP Pty Ltd Unit 5/118 Church St Hawthorn, VIC, 3122 Australia

Sponsor:

Southern XP IP Pty Ltd Unit 5/118 Church Street Hawthorn, 3122, Victoria Australia

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