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Package leaflet: Information for the patient

Sodium Nitroprusside 50 mg/2 mL Concentrate For Solution For Infusion

Sodium nitroprusside dihydrate

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Sodium Nitroprusside is and what it is used for
2. What you need to know before you use Sodium Nitroprusside
3. How to use Sodium Nitroprusside
4. Possible side effects
5. How to store Sodium Nitroprusside
6. Contents of the pack and other information

1. What Sodium Nitroprusside is and what it is used for

Sodium Nitroprusside is a medicine to lower blood pressure and to widen blood vessels, and is used in adults for:
- the treatment of high blood pressure crises (hypertensive crises)
- controlled blood pressure reduction in surgical procedures.

Sodium Nitroprusside is not suitable for long-term treatment.

2. What you need to know before you use Sodium Nitroprusside

Do not use Sodium Nitroprusside
- if you are allergic to the active substance sodium nitroprusside.
- if you have high blood pressure due to hereditary abnormal narrowing of the aorta (aortic isthmus stenosis) or shunting between arterial and venous blood vessels.
- if you have a hereditary degeneration of fibres of the optic nerve (Leber's hereditary optic atrophy).
- if you have both-sided, usually irreversible decrease in colour vision due to long-lasting tobacco abuse (tobacco amblyopia). This condition may occur, when the body is unable to get rid of toxic cyanide from the tobacco.
- if you have vitamin B12 deficiency.
- if you have increased acid level of the blood and body (metabolic acidosis).
- if you have an underactive thyroid (hypothyroidism).
- if you have shunting between arterial and venous blood vessels inside the lungs (intrapulmonary arteriovenous shunts). Arterial vessels (arteries) are leading blood from the heart to your organs; venous vessels (veins) are leading blood from the organs to your heart.

Warnings and precautions
Talk to your doctor or nurse before using Sodium Nitroprusside if you:
- have previously taken sildenafil or tadalafil or vardenafil. These medicines are used to achieve an erection in men or to lower blood pressure in blood vessels of the lungs. Sodium Nitroprusside should only be used after a strict benefit risk assessment, as it may lead to a pronounced increase in the blood pressure lowering effect in this case.
- have a disease associated with increased pressure in the skull.

Sodium nitroprusside infusions must only be administered with simultaneous administration of sodium thiosulfate solution. See information for healthcare professionals.

During the infusion of Sodium Nitroprusside, continuous monitoring of the ECG and of the blood flow is required.

Children and adolescents
The safety and efficacy of this drug in children and adolescents have not been demonstrated so far. No data are available. Therefore, this medicine should not be administered to children and adolescents.

Patients with renal impairment
If sodium nitroprusside is infused over several days (in case of high doses already within 24 hours), thiocyanate levels must be monitored especially in renally impaired patients and must not exceed 6 mg/100 mL.

Patients with hepatic impairment
Sodium Nitroprusside should be used with caution in patients with liver disease (hepatic impairment) and signs of cyanide toxicity should be monitored more closely (see section 4). If necessary, administration of sodium nitroprusside is to be gradually reduced or discontinued.

Other medicines and Sodium Nitroprusside
Tell your doctor if you are using, have recently used or might use any other medicines.

The concomitant administration of the following medicines can increase the blood pressure lowering effect of Sodium Nitroprusside:
- medicines to lower blood pressure and dilate blood vessels;
- medicines to lower blood pressure in blood vessels of the lung;
- sedatives
- anaesthetics

This especially applies after previous intake of sildenafil, tadalafil or vardenafil (see "Warnings and precautions").

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before using this medicine.

Experience during pregnancy and breast-feeding is insufficient, and Sodium Nitroprusside should only be used during this time if your doctor thinks it is absolutely necessary (that means, only following strictest indication).

3. How to use Sodium Nitroprusside

Sodium Nitroprusside is administered by a doctor or nurse by infusion into a vein using a suitable infusion pump.

The duration of administration is based among others on the overall dose: see information for healthcare professionals.

Sodium nitroprusside infusions generally have to be started with a low dose, and the dose is then doubled every 3-5 minutes until the desired blood pressure level is achieved. The blood pressure lowering effect is immediate. Towards the end of the infusion, the infusion rate is gradually reduced. Blood pressure will be measured frequently during the administration.

To achieve controlled low blood pressure (hypotension) during surgical procedures, it is recommended not to exceed the total amount of 1.0 to 1.5 mg/kg per patient.

To prevent cyanide poisoning (intoxication), it is strongly recommended always to administer a sodium thiosulfate solution simultaneously via a separate venous access. See information for healthcare professionals. For information about cyanide and thiocyanate intoxication, see "If you use more Sodium Nitroprusside than you should". For symptoms of cyanide and thiocyanate intoxication, see "Possible side effects". As an antidote in the event of suspected or observed cyanide toxicity (e.g., when no thiosulfate is available for co-administration), hydroxocobalamine and/or other agents to detoxify your blood might be required, see information for healthcare professionals.

Dosing tables and infusion rates for using a perfusor or an infusomat: see information for healthcare professionals.

Elderly
Elderly patients frequently require lower doses.

If you use more Sodium Nitroprusside than you should
Any intoxication can be avoided when the dosing instructions are observed.

Cyanide intoxication
In case of cyanide intoxication, the infusion dose of Sodium Nitroprusside should be reduced and, if necessary, cyanide should be removed from the body by an antidote. For further information, see "How to use Sodium Nitroprusside".

In case of thiocyanate intoxication, the infusion of this drug should be discontinued and, if necessary, thiocyanate should be removed from the body via dialysis.

For symptoms of cyanide and thiocyanate toxicity, see section 4 "Possible side effects".
If you have any further questions on the use of this medicine, ask your doctor or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

During treatment of high blood pressure, symptoms such as weakness, dizziness, nausea, vomiting and increased heart rate (tachycardia) can occur.

Frequency not known

Further possible side effects are:
- reactions at the application site (pain, skin reddening, itching)
- excessive blood pressure reduction
- nausea, vomiting, diarrhoea, incontinence
- ringing in the ears
- confusion
- hallucinations
- transient narrowing of the pupils
- increased tendency of reflexes
- temporary increase of signs of illness (rebound effect)

An insufficient decrease in blood pressure, decreased effect with repeated administration of this drug (tachyphylaxis) and tolerance are more commonly expected in younger than in older patients with high blood pressure.

Cyanide toxicity may manifest as
- bright red venous blood
- flat and/or slow breathing (hypoventilation)
- increased lactate
- decreased oxygen uptake
- feeling your heartbeat (palpitations), irregular heartbeat
- headache
- metabolic increased acid level in the blood and body (metabolic acidosis)
- coma, breathing paralysis, seizures

Deaths have been reported.

Such signs of toxicity can occur if the amount of cyanide is so high that the human body is not able to manage such poisoning; thus a parallel administration of sodium thiosulfate is needed.

Cyanide intoxication is completely avoidable by simultaneously administering a sodium thiosulfate infusion.

Symptoms of **thiocyanate toxicity** that can occur in case of overdose - earlier in patients with kidney problems than in patients with healthy kidneys – include:
- dizziness, headache, loss of appetite
- sleep disorders, nervousness
- underactive thyroid
- diarrhoea, vomiting, incontinence
- psychosis
- paralysis and coma

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The following information is intended for healthcare professionals only:

Dosing instructions, method and duration of administration
Sodium Nitroprusside is infused intravenously via a perfusor (see Table 1) or infusomat. Among others, the duration of administration is based on the total dosage: see information for healthcare professionals under "Warnings and precautions for use" and "Overdose and other administration errors".

Sodium Nitroprusside is a concentrated aqueous solution (50 mg/2 mL), which has to be diluted with 5% glucose solution prior to administration. The final concentration of the diluted product (1.0 mg/mL) may differ from the final concentration of other reconstituted products on the market, which is due to different amounts of nitroprusside sodium per unit. However, the administered dosage is the same, when the infusion rates recommended in Table 1 for Sodium Nitroprusside are followed. The volume ratios of sodium nitroprusside to sodium thiosulfate solution provided in the section "Prevention of cyanide toxicity" and in Table 2 should be used.

Sodium nitroprusside infusions generally have to be started with low doses. The hypotensive effect is immediate. Baseline values are rapidly achieved after the end of the infusion. In the titration phase, an exact titration with blood pressure measurements every one to two minutes is required. Towards the end of the infusion, the infusion rate is gradually reduced.

The infusion is started at a dose of 0.2 µg/kg/min. It is then doubled every 3 to 5 minutes until the desired blood pressure level is achieved. The infusion rate varies between 0.2 and 10 µg/kg/min; see Table 1 below.

To achieve controlled hypotension during surgical procedures, it is recommended not to exceed the total amount of 1.0 to 1.5 mg/kg per case.

In case of sodium nitroprusside infusions administered over several days, e.g. for the treatment of hypertensive crises, the maximum doses stated above are generally exceeded.

Table 1: Dosage table for 1 mg/mL sodium nitroprusside dihydrate using a 50 mL syringe pump

µg/kg/min sodium nitroprusside dihydrate	Infusion rate [mL/h]														
	Body weight [kg]														
	30	35	40	45	50	55	60	65	70	75	80	85	90	95	100
0.2	0.4	0.4	0.5	0.5	0.6	0.7	0.7	0.8	0.8	0.9	1.0	1.0	1.1	1.1	1.2
0.4	0.7	0.8	1.0	1.1	1.2	1.3	1.4	1.6	1.7	1.8	1.9	2.0	2.2	2.3	2.4
0.8	1.4	1.7	1.9	2.2	2.4	2.6	2.9	3.1	3.4	3.6	3.8	4.1	4.3	4.6	4.8
1.0	1.8	2.1	2.4	2.7	3.0	3.3	3.6	3.9	4.2	4.5	4.8	5.1	5.4	5.7	6.0
1.6	2.9	3.4	3.8	4.3	4.8	5.3	5.8	6.2	6.7	7.2	7.7	8.2	8.6	9.1	9.6
3.2	5.8	6.7	7.7	8.6	9.6	10.6	11.5	12.5	13.4	14.4	15.4	16.3	17.3	18.2	19.2
5.0	9.0	10.5	12.0	13.5	15.0	16.5	18.0	19.5	21.0	22.5	24.0	25.5	27.0	28.5	30.0
6.4	11.5	13.4	15.4	17.3	19.2	21.1	23.0	25.0	26.9	28.8	30.7	32.6	34.6	36.5	38.4
10.0	18.0	21.0	24.0	27.0	30.0	33.0	36.0	39.0	42.0	45.0	48.0	51.0	54.0	57.0	60.0

Prevention of cyanide toxicity
To effectively prevent cyanide intoxication, it is strongly recommended to administer the sodium nitroprusside infusion always with a simultaneous continuous infusion of a sodium thiosulfate solution via a separate venous access at a ratio of approx. 1:10 (sodium nitroprusside dihydrate: sodium thiosulfate) based on the weights of the active substances.

Concerning the practical procedure, it is recommended to draw up sodium thiosulfate solution 100 mg/mL into a second Perfusor syringe and to infuse it at a volume ratio of approx. 12:1 (sodium nitroprusside dihydrate: sodium thiosulfate) via a separate venous access as indicated in Table 2 below.

When using an Infusomat for Sodium Nitroprusside, the volume ratio should be 60:1 or 120:1 (see also table 2).

As an antidote in the event of suspected or observed cyanide toxicity (e.g., when no thiosulfate is available for co-administration), hydroxocobalamine and/or methaemoglobin-forming agents might be required. The respective safety information of these medications must be followed.

Thiocyanate toxicity
If Sodium Nitroprusside infused over several days (in case of high doses already within 24 hours), thiocyanate levels must be monitored especially in renally impaired patients and must not exceed 6 mg/100 mL. Thiocyanate concentrations of more than 6 mg/100 mL lead to toxic symptoms such as weakness, vomiting, dizziness and tinnitus. In cases of thiocyanate intoxication, the infusion of sodium nitroprusside should be discontinued and, if necessary, thiocyanate should be removed from the body with the help of dialysis.

Elderly patients
Elderly patients frequently require lower doses.

Paediatric population
The safety and efficacy of Sodium Nitroprusside in children and adolescents have not been demonstrated so far. No data are available. Therefore, Sodium Nitroprusside should not be administered to children and adolescents.

Patients with renal impairment
If sodium nitroprusside is infused over several days (in case of high doses already within 24 hours), thiocyanate levels must be monitored, especially in renally impaired patients and must not exceed 6 mg/100 mL.

Patients with hepatic impairment
Because the cyanide, which is released from sodium nitroprusside, is mainly metabolized by hepatic enzymes, it may accumulate in patients with severe hepatic impairment. Sodium Nitroprusside should therefore be used with caution in patients with hepatic impairment and dose titration must be done carefully. In patients with hepatic impairment, signs of cyanide toxicity should be monitored more closely (see section 4.8). If necessary, administration of sodium nitroprusside is to be gradually reduced or discontinued, and the instructions for treatment of cyanide toxicity must be followed.

Concentrate for solution for infusion
The solution in vials before diluting has a reddish brownish colour and should never be injected directly. For further dilution only a solution of 5% glucose may be used. The solution for infusion containing sodium nitroprusside must be prepared immediately prior to the administration.

Note
The ready-to-use solution for infusion is sensitive to light. Protection against light is possible by using coloured syringes and hoses. The infusion bags should be

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Very high serum concentrations can lead to death.

The thiocyanate intoxication can be avoided when the dosing instructions are observed. In case of thiocyanate intoxication, the infusion of this drug should be discontinued and, if necessary, thiocyanate should be removed from the body via dialysis.

Reporting of side effects
If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme, website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Sodium Nitroprusside

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Keep the vials in the outer carton in order to protect from light.

Expiration date after reconstitution
Protect the ready-to-use preparation from light by using coloured syringes and hoses.

The in-use stability (chemical and physical in-use stability) of the solution for infusion has been demonstrated 24 hours at 25 °C ± 2 °C when protected from light (when a Perfusor light-protective syringe is used).

From a microbiological point of view (such as bacterial growth), the solution for infusion should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 25 °C ± 2 °C, unless reconstitution/dilution has taken place under controlled and validated conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Sodium Nitroprusside contains
- The active substance is sodium nitroprusside. Each vial contains 50 mg sodium nitroprusside dihydrate, equivalent to 44 mg anhydrous sodium nitroprusside.
- The other ingredient (excipient) is water for injections.

What Sodium Nitroprusside looks like and contents of the pack
Clear reddish-brown solution for infusion in 2 mL amber-coloured glass vials with a rubber stopper and aluminium-plastic overseal.

Pack size: each carton contains 1 vial of 2 mL.

A light-protecting sleeve is included in the unit pack for overwrapping the infusion bag containing the solution for infusion with added sodium nitroprusside solution.

Marketing Authorisation Holder and Manufacturer

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AFT Pharma UK Limited
Milner House
14 Manchester Square
London W1U 3PP
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Sodium Nitroprusside 50 mg/2 mL Concentrate For Solution For Infusion

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overwrapped with the light-protective sleeve included in the unit packs.

Chemical and physical in-use stability of the solution for infusion has been demonstrated for 24 hours at 25 °C ± 2 °C, when protected from light (using a light-protective Perfusor syringe). From a microbiological point of view, the solution for infusion should be used immediately. If not used immediately, the storage time and conditions prior to use are the responsibility of the user and should not be longer than 24 hours at 25 °C ± 2 °C, unless dilution has taken place at controlled and validated conditions.

The solution for infusion is clear colourless to faint brownish. Strongly coloured solutions for infusion must not be used. Additional drugs must not be added to the ready-to-use solution for infusion. The safest way to administer the solution for infusion is via a separate venous catheter to prevent an accumulation of active substances in the tube system or in peripheral veins.

Perfusor (see also dosing Table 1)
When using a perfusor, add 2.0 mL of Sodium Nitroprusside to 48 mL of a 5% glucose solution to obtain 50 mL of a 1 mg/mL solution of sodium nitroprusside. 48 mL of the 5% glucose solution is first drawn up into a 50 mL Perfusor syringe. Then 2.0 mL of the Sodium Nitroprusside is added to the Perfusor syringe using a 2 mL syringe. To prevent overdoses, the content of the perfusor syringe must be homogeneously mixed by **shaking**.

Infusomat (see also Table 2)
When using an infusomat, 2.0 mL of solution from one vial of Sodium Nitroprusside is injected into 250 mL or 500 mL of a 5% glucose solution. For controlled intraoperative hypotension, the dilution in 250 mL is recommended. The dose conversion is detailed in the dosage table (Table 1). The infusion rates indicated in Table 1 in mL per hour are multiplied by a factor 5 when diluting in 250 mL of glucose solution, and with a factor 10 when diluting in 500 mL. To prevent a high fluid load, the perfusor is the preferred method for prolonged infusions.

Any unused medicinal product or waste material should be discarded in accordance with local regulations.

Table 2

Dosage Sodium Sodium Nitroprusside			**Dosage sodium thiosulfate 100 mg/mL**
Perfusor in 50 mL	**Infusomat in 250 mL**	**Infusomat in 500 mL**	**Perfusor**
1 - 12 mL/h	6 - 60 mL/h	12 - 120 mL/h	1 mL/h
13 - 24 mL/h	61 - 120 mL/h	121 - 240 mL/h	2 mL/h
25 - 36 mL/h	121 - 180 mL/h	241 - 360 mL/h	3 mL/h
37 - 48 mL/h	181 - 240 mL/h	361 - 480 mL/h	4 mL/h

Overdose and other administration errors

Emergency measures, symptoms and antidotes
In case of an acute myocardial infarction, an excessive reduction of aortic pressure bears the risk of a decrease in diastolic coronary perfusion. In case of acute cardiac failure with decreased filling pressures, the cardiac output may continue to drop.

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Tachyphylaxis and rebound phenomenon are possible.

Cyanide intoxication can occur during the treatment with Sodium Nitroprusside. This depends on the duration of treatment and on the dose level. Short-term treatment with sodium nitroprusside dihydrate 2.5 µg/kg/min is safe. By contrast,
- 5 µg/kg/min after 10 hours,
- 10 µg/kg/min after 4 hours and
- 20 µg/kg/min after 1.5 hours

can lead to life-threatening cyanide levels.

Therapeutic countermeasures include reducing the infusion dose or administering an antidote.

In case of cyanide intoxication, 4-Dimethylaminophenol Hydrochloride (4-DMAP) 3 to 4 mg/kg i.v. (produces methaemoglobin) is recommended as a short-acting antidote. This is followed by an infusion of sodium thiosulfate, 50 to 100 mg/kg body weight.

In cases of thiocyanate intoxication, the infusion of sodium nitroprusside should be discontinued and, if necessary, thiocyanate should be removed from the body via dialysis.

For more information, see also “Warnings and precautions for use” as well as “Dosing instructions, method and duration of administration” of the information for healthcare professionals.

Warnings and precautions for use
During the infusion of Sodium Nitroprusside, continuous monitoring of the ECG and, where relevant, of the most important haemodynamic parameters is required. Under surgical conditions, the best way to measure blood pressure is directly via an arterial cannula. In case of infusions administered over several days, blood pressure measurements by a non-invasive technique are sufficient.

Warning
In cases of patients who have previously taken PDE 5 inhibitors, the application of Sodium Nitroprusside should only occur subject to strict risk/benefit consideration.

For PDE 5 inhibitors a significant intensification of the hypotensive effect of Sodium Nitroprusside may occur, if sodium nitroprusside is given in the 24 hours post-dose sildenafil or vardenafil, or 48 hours post-dose tadalafil, depending on the half-life of the PDE 5 inhibitor.

In this case, particularly careful dose titration of Sodium Nitroprusside is required.

For pharmacological, pharmacokinetic and toxicological properties, see section 5 of the SmPC.

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GENERAL INFO:

PRODUCT NAME:	**Nitroprusside-AFT 50 mg/2 mL**
TERRITORY:	ENG
AW VERSION:	v1
CREATION DATE:	29.04.2025

TECHNICAL INFO:

FORMAT (size):	450 x 286
LAETUS (pharma code):	XXXX
FONT + MIN. SIZE:	Helvetica Neue LT W1G 8,5 pt
LEADING:	3 mm

COLOURS: [1]

■ Black

TECH. COLOURS: [1]

■ DieCut

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