SODIUM NITROPRUSSIDE

Product information that stands out

Packaging is InformatIV™
- Easy-to-read drug name and strength
- Use instructions and a caution prominently displayed on label and carton
- Sleeve to protect the infusion solution against light degradation included
- Available in single-dose 50 mg per 2 mL amber glass vials
- Preservative-free, AP rated, bar coded and not made with natural rubber latex

SODIUM NITROPRUSSIDE Injection

Please see full prescribing information, including boxed warning, for SODIUM NITROPRUSSIDE Injection, enclosed.

Every SAGENT® Product Features...

SAGENT Pharmaceuticals®
Discover Injectables Excellence®
SODIUM NITROPRUSSIDE Injection

Innovator Product Name: NITROPRESS®
(Nitropress is a registered trademark of Hospira Inc.)

INDICATIONS AND USAGE
Sodium nitroprusside is indicated for the immediate reduction of blood pressure of adult and pediatric patients in hypertensive crises. Concomitant longer-acting antihypertensive medication should be administered so that the duration of treatment with sodium nitroprusside can be minimized.

Sodium nitroprusside is also indicated for producing controlled hypotension in order to reduce bleeding during surgery and for the treatment of acute congestive heart failure.

CONTRAINDICATIONS
• Sodium nitroprusside should not be used in patients with known inadequate cerebral circulation, or in moribund patients (A.S.A. Class SE) coming to emergency surgery.
• Administration of sodium nitroprusside should be avoided in patients with congenital (Leber’s) optic atrophy or with tobacco amblyopia.
• Sodium nitroprusside should not be used for the treatment of acute congestive heart failure associated with reduced peripheral vascular resistance.

WARNINGS
• The principal hazards of Sodium Nitroprusside administration are excessive hypotension and excessive accumulation of cyanide.
• Small transient excesses in the infusion rate of sodium nitroprusside can result in excessive hypotension. Nitroprusside-induced hypotension will be self-limited within 1 to 10 minutes after discontinuation of the nitroprusside infusion; during these few minutes, it may be helpful to put the patient into a head-down (Trendelenburg) position to maximize venous return.

ADVERSE REACTIONS
• The most important adverse reactions to sodium nitroprusside are the avoidable ones of excessive hypotension and cyanide toxicity.
• Sodium nitroprusside infusions can cause sequestration of hemoglobin as methemoglobin. When methemoglobinemia is diagnosed, the treatment of choice is 1 to 2 mg/kg of methylene blue, administered intravenously over several minutes.
• When cyanide elimination is accelerated by the co-infusion of thiosulfate, thiocyanate production is increased.

OVERDOSAGE
Overdosage of nitroprusside can be manifested as excessive hypotension or cyanide toxicity. Treatment of cyanide toxicity consists of discontinuing the administration of sodium nitroprusside, providing a buffer for cyanide by using sodium nitrite to convert as much hemoglobin into methemoglobin as the patient can safely tolerate, and then infusing sodium thiosulfate in sufficient quantity to convert the cyanide into thiocyanate. Hemodialysis is ineffective in removal of cyanide, but it will eliminate most thiocyanate.

Please see full prescribing information for SODIUM NITROPRUSSIDE Injection.
**Sodium Nitroprusside Injection**

**DESCRIPTION**
Sodium nitroprusside is a disulfide (pentylamino[4-formamido]-2,4-dithiolate), a hypotensive agent whose structural formula is:

![Structural formula of sodium nitroprusside](image)

In its intravenous base, sodium nitroprusside is sodium nitroprusside dihydrate in sterile water for injection. 50 mg Flip-top Vial – Each 2 mL vial contains the equivalent of 50 mg sodium nitroprusside dihydrate, a hypotensive agent whose structural formula is:

![Structural formula of sodium nitroprusside dihydrate](image)

**Pharmacology and Metabolism**
Sodium nitroprusside is rapidly distributed to a volume that is approximately equivalent to the extracellular space. The drug is cleared from the body by converting to cyanmethemoglobin. Sodium nitroprusside is excreted into the urine and is stable to normal temperatures up to 50°C. Unlike other drugs used to produce a hypotensive effect, sodium nitroprusside is metabolized by the liver; the major metabolite is cyanmethemoglobin.

**CLINICAL PHARMACOLOGY**
The principal pharmacological action of sodium nitroprusside is relaxation of vascular smooth muscle, and consequent decrease in venous return to the heart, thereby reducing left ventricular afterload. The effect is not affected. Sodium nitroprusside is more active on veins than arteries.

**INDICATIONS AND USAGE**
Sodium nitroprusside is indicated for the immediate reduction of blood pressure in patients with known inadequate cerebral circulation, or in those patients for whom other vasodilators are considered inappropriate, for example, dobutamine.

**SIDE EFFECTS**
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The effects of administering sodium thiosulfate in pregnancy, either by itself or as a co-infusion with sodium nitroprusside, are completely unknown.

Mechanism of Action
Sodium thiosulfate is administered as an intravenous (IV) bolus as a single dose or as an infusion. It is rapidly and completely absorbed into the systemic circulation. The drug is eliminated renally.

Pharmacology
The mean volume of distribution is large (1 to 2 liters/kg) and is independent of dose. The drug is not bound to plasma proteins. Metabolites are not formed. The drug is excreted in the urine (95% in the first 24 hours).

Targets
The primary effect is to bind cyanide in the plasma, thereby preventing its further exertion. Because the drug binds only to free cyanide, it does not interact with other cyanides that are bound to thiocyanate. Therefore, it does not affect the levels of other cyanides such as hydrogen cyanide or thiocyanate.

Dosage and Administration
The usual dose is 1 to 2 mg/kg of methylene blue, administered intravenously over one to two minutes.

Adverse Effects
Adverse effects are few and transient. These may include fever, hypotension, headache, nausea, vomiting, diarrhea, tachycardia, flushing, and rarely, hypokalemia.

Drug Interactions
Sodium nitroprusside should not be administered in the same IV line with other drugs simultaneously. This is due to the possibility of an in vivo interaction between sodium nitroprusside and other drugs, which could result in an altered therapeutic effect or increased toxicity.

Indications
Sodium nitroprusside is used for the acute treatment of severe hypertension, particularly when rapid control of blood pressure is required, such as in patients with severe aortic stenosis, acute myocardial infarction, or renal failure.

Contraindications
Sodium nitroprusside is contraindicated in patients with a history of hypersensitivity to nitroprusside or to any of its components, as well as in patients with significant hypotension or hypovolemia.

Precautions
Sodium nitroprusside is a potent vasoconstrictor and should be used cautiously in patients with a history of cardiac disease, especially those with a history of hypertension, coronary artery disease, or congestive heart failure.

Dosage
The recommended dosage of sodium nitroprusside ranges from 50 to 500 mg, administered by continuous IV infusion. The rate of infusion should be titrated to achieve the desired blood pressure with minimal side effects.

Limitations
Sodium nitroprusside has a limited half-life of approximately 1 to 2 minutes, requiring frequent adjustments to the infusion rate to maintain effective blood pressure control. It is important to monitor blood pressure and other vital signs closely during therapy.

Clinical Experience
Sodium nitroprusside has been used in a variety of clinical settings, including acute coronary syndrome, left ventricular dysfunction, and severe hypertension in adults and children. It has also been used in the management of hypertensive emergencies, such as preeclampsia and severe preeclampsia.

Sodium nitroprusside has been shown to be effective in reducing blood pressure in patients with refractory hypertension, particularly in those with severe aortic stenosis and in patients who are intolerant to other antihypertensive agents.

Sodium nitroprusside is metabolized in the liver, and the major metabolite is cyanide. The conversion of nitroprusside to cyanide is rapid, and the cyanide levels in the plasma and urine can be measured to monitor drug levels and to assess the potential for adverse effects.

Thiocyanate Toxicity
Thiocyanate toxicity is reported to occur in approximately 1 in 10,000 patients, and it is more common in children. The symptoms of thiocyanate toxicity include nausea, vomiting, tachycardia, and agitation.

Thiosulfate Treatment
Thiosulfate treatment is recommended for patients who develop symptoms of thiocyanate toxicity. The standard dose is 1 to 2 mg/kg of methylene blue, administered intravenously over one to two minutes.

Thiosulfate is a strong reducing agent and is used to convert cyanide to thiocyanate. It is rapidly and completely absorbed and is eliminated renally.

Sodium Thiosulfate Injection
Sodium thiosulfate is available as a 10% solution, which is administered intravenously. The dose is titrated to achieve the desired effect, with monitoring of vital signs and blood pressure.

References