SODIUM NITROPRUSSIDE Injection*

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SODIUM NITROPRUSSIDE Injection*

Brand Name Equivalent: NITROPRESS® (NITROPRESS is a registered trademark of Hospira, Inc.)

Therapeutic Category: Cardiovascular

Benefits:
- AP Rated
- Preservative-free
- Not made with natural rubber latex

Available in:
- 50 mg per 2 mL single-dose vials

Sodium Nitroprusside Injection is not suitable for direct injection. The solution must be further diluted in sterile 5% dextrose injection before infusion.

Sodium Nitroprusside can cause precipitous decreases in blood pressure (see DOSAGE AND ADMINISTRATION). In patients not properly monitored, these decreases can lead to irreversible ischemic injuries or death. Sodium nitroprusside should be used only when available equipment and personnel allow blood pressure to be continuously monitored.

Except when used briefly or at low (< 2 mcg/kg/min) infusion rates, sodium nitroprusside gives rise to important quantities of cyanide ion, which can reach toxic, potentially lethal levels (see WARNINGS). The usual dose rate is 0.5 to 10 mcg/kg/min, but infusion at the maximum dose rate should never last more than 10 minutes. If blood pressure has not been adequately controlled after 10 minutes of infusion at the maximum rate, administration of sodium nitroprusside should be terminated immediately.

Although acid-base balance and venous oxygen concentration should be monitored and may indicate cyanide toxicity, these laboratory tests provide imperfect guidance.

*Please see full prescribing and safety information, including boxed warning.
<table>
<thead>
<tr>
<th>Storage Requirement</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tr>
</tbody>
</table>

SODIUM NITROPRUSSIDE Injection*

*Please see full prescribing and safety information, including boxed warning, for SODIUM NITROPRUSSIDE.
SODIUM NITROPRUSSIDE Injection*

*Please see full prescribing and safety information, including boxed warning, for SODIUM NITROPRUSSIDE vials.
SODIUM NITROPRUSSIDE Injection*

*Please see full prescribing and safety information, including boxed warning, for SODIUM NITROPRUSSIDE vials.
Sodium Nitroprusside Injection

**INDICATIONS AND USAGE**

Sodium nitroprusside is indicated for the immediate reduction of elevated perfusion pressure in patients whose hypotension is not satisfactorily controlled by other available antihypertensive agents. It is used in association with other antihypertensive agents, including epinephrine and ephedrine, to achieve blood pressure levels which are not usually attainable with these agents alone.

**CONTRAINDICATIONS**

Sodium nitroprusside is contraindicated in patients with a known allergy to sodium nitroprusside or to thiocyanate (formed from sodium nitroprusside).

**WARNINGS**

Sodium nitroprusside has the potential for cyanide toxicity. The effects of cyanide toxicity can be instantaneous and are dominated by respiratory depression with brain death often occurring prior to clinical signs of tissue death.

**OVERDOSAGE**

The usual dose is 0.5 to 10 mcg/kg/min, but rates, sodium nitroprusside gives rise to important quantities of cyanide, causing hypoxia. The usual dose is 0.5 to 10 mcg/kg/min.

**DOSAGE AND ADMINISTRATION**

Sodium nitroprusside is administered by continuous intravenous infusion. The usual dose rate is 0.5 to 10 mcg/kg/min, but sodium nitroprusside may be used in doses of up to 10 mcg/kg/min for severe hypertension. The maximum dose rate for most patients is 10 mcg/kg/min.

**ADVERSE REACTIONS**

Cyanide toxicity may manifest itself as symptoms such as headache, vomiting, dizziness, ophthalmoplegia, drowsiness, hypothermia, tachypnea, and cyanosis. The symptoms may appear during treatment or may be delayed. The symptoms are usually reversible if treatment is instituted promptly. The treatment consists of administering oxygen by face mask or bag and mask ventilation if necessary.
As described in Thiocyanate Toxicity, extreme caution. Several minutes. In patients likely to have substantial amounts of cyanide to 1 mg/kg of methylene blue, administered intravenously over without color change on exposure to air.

Classically, methemoglobinemic blood is described as chocolate brown, muscle twitching, nausea, palpitations, restlessness, retching, and is.

Thiocyanate interferes with iodine uptake by the thyroid.

Methemoglobinemia As described in CLINICAL PHARMACOLOGY above, sodium nitroprusside infusion can cause severe methemoglobinemia, which is described in the text. Sodium methemoglobinemia (5%) is seen rarely in patients receiving Sodium Nitroprusside. Even patients concomitantly receiving blood, which can be treated with 2 mg/kg of methylene blue; this level of methemoglobinemia is not associated with systemic toxicity. In a patient not in shock, 2 mg/kg of sodium nitroprusside may be delayed. In a patient who is already in shock, 10 mcg/kg/min would be administered. Since methemoglobinemia is avoidable, and all of the precautions concerning sodium nitroprusside administration must still be observed.

Thiocyanate toxicity as described in CLINICAL PHARMACOLOGY above, most of the cyanide produced during metabolism of sodium nitroprusside is eliminated in the form of thiocyanate. When cyanide metabolism is accelerated by co-infusion of thiocyanate, thiocyanate production is increased.

This is normal and is the result of differences in the patient's cardiovascular system. Thiocyanate levels in sodium nitroprusside are 2.8, 5.0, 8.4, and 11.2 mg/kg, respectively.

Hematologic: Anemia, thrombocytopenia, leukopenia, hypocalcemia, multifocal cutaneous petechiae, purpura, and rash. Mucous membranes may be pale.

Rash.

Hypothyroidism.
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

Every SAGENT® Product Features...

SODIUM NITROPRUSSIDE Injection

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

Every SAGENT® Product Features...

PreventIV Measures™ Packaging and Labeling

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
• Patients with congenital (Leber’s) optic atrophy or with tobacco amblyopia have an unusually high cyanide/thiocyanate ratio. These rare conditions are probably avoided in these patients.
• Sodium nitroprusside should not be used to produce hypotension during surgery in patients with known inadequate cerebral circulation, or in moribund patients (A.S.A. Class 5E) coming to emergency surgery.
• Sodium nitroprusside should be used only when available equipment and personnel allow blood pressure to be continuously monitored.

WARNINGS
• Sodium Nitroprusside Injection is not suitable for direct injection. The solution must be further diluted in sterile 5% dextrose solution before infusion.
• Sodium Nitroprusside can cause precipitous decreases in blood pressure (see DOSAGE AND ADMINISTRATION). In patients not properly monitored, these decreases can lead to irreversible ischemic injuries or death. Sodium nitroprusside should be used only when available equipment and personnel allow blood pressure to be continuously monitored.
• Sodium Nitroprusside infusions at rates above 2 mcg/kg/min generate cyanide ion (CN−) faster than the body can normally dispose of it. When sodium thiosulfate is given, as described under DOSAGE AND ADMINISTRATION, the body’s capacity for CN− elimination is greatly increased.
• Cyanide toxicity may manifest itself as venous hyperoxemia with bright red venous blood, as cells become unable to extract the oxygen delivered to them; metabolic (lactic) acidosis; air hunger; confusion; and death.
• Hypertensive patients, and patients concomitantly receiving other antihypertensive medications, may be more sensitive to the effects of sodium nitroprusside than normal subjects.

PRECAUTIONS
• Like other vasodilators, sodium nitroprusside can cause increases in intracranial pressure. In patients whose intracranial pressure is already elevated, sodium nitroprusside should be used only with extreme caution.
• Use caution when administering nitroprusside to patients with hepatic insufficiency.
• When sodium nitroprusside (or any other vasodilator) is used for controlled hypotension during anesthesia, the patient’s capacity to compensate for anemia and hypovolemia may be diminished. If possible, pre-existing anemia and hypovolemia should be corrected prior to administration of Sodium Nitroprusside.
• The hypotensive effect of sodium nitroprusside is augmented by that of other hypotensive drugs, including ganglionic blocking agents, negative inotropic agents, and inhaled anesthetics.
• It is not known whether Sodium Nitroprusside can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Sodium Nitroprusside should be given to a pregnant woman only if clearly needed.
• The effects of administering sodium thiosulfate in pregnancy, either by itself or as a co-infusion with sodium nitroprusside, are completely unknown.
• It is not known whether sodium nitroprusside and its metabolites are excreted in human milk.

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 resequestration of hemoglobin as methemoglobin. The back-conversion process is normally rapid, and clinically significant methemoglobinemia (>10%) is seen only rarely in patients receiving Sodium Nitroprusside. When methemoglobinemia is diagnosed, the treatment of choice is 1 to 2 mg/kg of methylene blue, administered intravenously over several minutes.
• Most of the cyanide produced during metabolism of sodium nitroprusside is eliminated in the form of thiocyanate. When cyanide elimination is accelerated by the co-infusion of thiosulfate, thiocyanate production is increased.
• Other adverse reactions reported are bradycardia, electrocardiographic changes, tachycardia, rash, hypothyroidism, ileus, decreased platelet aggregation, increased intracranial pressure, flushing, venous streaking and irritation at the infusion site.

OVERDOSAGE
Overdose 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.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Please see full prescribing information for SODIUM NITROPRUSSIDE Injection.

This SAGENT product meets stringent FDA requirements and is AP rated, preservative-free and not made with natural rubber latex.

To order, or for more information about how to Discover Injectables Excellence® with SAGENT, contact your sales representative, call 1-866-625-1618 or visit www.SagentPharma.com.

Listening. Responding. Delivering. That’s Injectables Excellence. That’s SAGENT Pharmaceuticals®

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PreventIV Measures and Information are service marks of Sagent Pharmaceuticals, Inc.

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Sodium Nitroprusside Injection

**DESCRIPTION**

Sodium nitroprusside is a disodium pentacyanoferrate(II) dihydrate, a hypotensive agent whose structural formula is:

\[
2Na^+ \cdot (Fe(CN)_5OH)^- \cdot H_2O
\]

Cyanide ion is normally found in serum; it is derived from dietary sources and is excreted in the urine. Cyanide is not found in normal body fluids in amounts that can be measured with the commonly used laboratory techniques.

Cyanide is a potent inhibitor of cytochrome oxidase and of other enzymes that require iron and copper for their activity. Cyanide is also the terminal acceptor in the electron transport chain of all tissues that use oxygen as a fuel in the production of energy. Cyanide toxicity results from the inhibition of mitochondrial cytochrome oxidase, which impairs the ability of the tissue to utilize oxygen.

The effects of sodium nitroprusside to induce hypotension were evaluated in two trials in pediatric patients less than 17 years of age. In both trials, at least 50% of the patients were pre-pubertal, and about 50% of these pre-pubertal patients were less than 2 years of age, but the capacity of this system is exhausted in patients who are very elderly or in patients who are very young.

**INDICATIONS AND USAGE**

Sodium nitroprusside is indicated for the immediate reduction of elevated blood pressure in patients with known inadequate cerebral circulation, or in situations where the true cause must be sought.

**WARNINGS**

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

**CONTRAINDICATIONS**

Sodium nitroprusside should be used in patients with known inadequate cerebral circulation, or in situations where the true cause must be sought.

**ADVERSE REACTIONS**

Sodium nitroprusside is also indicated for treating patients with hyper- or hypothyroidism.

**DOSAGE AND ADMINISTRATION**

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

**INDICATIONS AND USAGE**

Sodium nitroprusside is indicated for the immediate reduction of elevated blood pressure in patients with known inadequate cerebral circulation, or in situations where the true cause must be sought.

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

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Sodium nitroprusside should be used in patients with known inadequate cerebral circulation, or in situations where the true cause must be sought.

**ADVERSE REACTIONS**

Sodium nitroprusside is also indicated for treating patients with hyper- or hypothyroidism.

**DOSAGE AND ADMINISTRATION**

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

bound to methemoglobin as cyanmethemoglobin, treatment of several minutes. In patients likely to have substantial amounts of cyanide.

Classically, methemoglobinemic blood is described as chocolate brown, muscle twitching, nausea, palpitations, restlessness, retching, and.

rate of the dialyzer.

levels of 1 mmol/L (60 mg/L). Thiocyanate toxicity is life-threatening. Thiocyanate is mildly neurotoxic (tinnitus, miosis, hyperreflexia) at serum.

the form of thiocyanate. When cyanide elimination is accelerated by the produced during metabolism of sodium nitroprusside is eliminated in.

infusion was slowed or discontinued, and they did not reappear with a.

The diagnosis should be suspected in patients who have received >10 accumulated dose.

converting methemoglobin should demonstrate 10% methemoglobinemia

The most important adverse reactions to sodium nitroprusside are the.

The adverse reactions described in this section

issues were seen in these studies in pediatric patients. See Clinical

Table 2: Infusion Rates (mL/hour) to Achieve Initial (0.3 mcg/kg/min) and Maximal (10 mcg/kg/min) Dosing of Sodium Nitroprusside

| pt weight | kg | lbs init max init max init max
<table>
<thead>
<tr>
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<tr>
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<td>360 540</td>
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<td>240 176</td>
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<td>45 22</td>
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<td>22 11</td>
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<tr>
<td>5 10 20</td>
<td>3</td>
<td>10 3</td>
<td>6 3</td>
<td>12 6</td>
<td></td>
</tr>
</tbody>
</table>

OVERDOSE

Sodium nitroprusside should

achieve the desired blood pressure.

min) and Maximal (10 mcg/kg/min) Dosing of Sodium Nitroprusside

Table 2: Infusion Rates (mL/hour) to Achieve Initial (0.3 mcg/kg/min) and Maximal (10 mcg/kg/min) Dosing of Sodium Nitroprusside

| Volume of Fluid | Concentration | kg lbs init max init max init max |
|-----------------|--------------|------------------|------------------|------------------|
| 200 mL | 100 mg | 200 mL | 100 mg |
| 300 mL | 150 mg | 300 mL | 150 mg |
| 500 mL | 250 mg | 500 mL | 250 mg |

Other adverse reactions reported are: Cardiovascular: Hypotension, diastolic, electrocardiographic changes, left bundle.

PHARMACOLOGY

issues were seen in these studies in pediatric patients. See Clinical

Efficacy in the pediatric population was established based on adult trials and supported by the data ranging that (Study 1) and an open label that of at least 12 hour infusion of a rate that allowed adequate MAP control (Study 2). Pediatric patients on sodium nitroprusside. No dose-adjustment issues were seen in these studies in pediatric patients. See Clinical Pharmacology andDosage and Administration. Adverse Reactions

This is not a complete list of adverse reactions. In rare instances, severe adverse reactions have been reported that are not known to be related to the use of sodium nitroprusside. These have included anaphylactic reactions, acute urticaria, angioedema, pericardial effusion, pleural effusion, pulmonary edema, and death.

Other adverse reactions reported are: Cardiovascular: Hypotension, diastolic, electrocardiographic changes, left bundle.

CLINICAL PHARMACOLOGY

issues were seen in these studies in pediatric patients. See Clinical

Efficacy in the pediatric population was established based on adult trials and supported by the data ranging that (Study 1) and an open label that of at least 12 hour infusion of a rate that allowed adequate MAP control (Study 2). Pediatric patients on sodium nitroprusside. No dose-adjustment issues were seen in these studies in pediatric patients. See Clinical Pharmacology andDosage and Administration. Adverse Reactions

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Other adverse reactions reported are: Cardiovascular: Hypotension, diastolic, electrocardiographic changes, left bundle.
Section 1 - Identification

(a) **Product Identifier:** Sodium Nitroprusside Injection

(b) **Product Code:** 25021-310
   - **Common/Trade Name:** NITROPRESS®
   - **Chemical Name:** Disodium pentacyanonitrosylferrate(2-) dihydrate
   - **Chemical Family:** Vasodilator

(c) **Product Use:** Relaxes both arterial and venous smooth muscle. Clinically, it is used as a hypotensive agent for short-term, rapid reduction of blood pressure in hypertensive emergencies

   **Product Type:** Regulated Prescription Drug

   **Container Information:** Vial

(d) **Distributor:** Sagent Pharmaceuticals, Inc., 1901 N. Roselle Rd, Suite 700, Schaumburg, IL 60195, 847-908-1600

(e) **Emergency Telephone:** 866-625-1618

Section 2 - Hazards Identification

(a) **Classification:**
   - U.S. OSHA Classification: Target Organ Toxin; Possible Irritant
   - GHS Classification: *In the EU, classification under GHS/CLP does not apply to certain substances and mixtures, such as medicinal products as defined in Directive 2001/83/EC, which are in the finished state, intended for the final user.

(b) **Signal Word**
   - **Hazard statement(s), Symbol(s):** This material should be considered a potent drug, and potentially irritating to the skin, eyes, and respiratory tract. Based on clinical use, possible target organs include the skin, eyes, blood, central nervous system, and cardiovascular system; Avoid aerosol generation and skin contact.
   - **Precautionary statement(s):** Pre-existing hypotension or pre-existing skin, eye, nervous system, blood, or cardiovascular ailments may be aggravated by exposure.
   - **P260 - Do not breathe dust/fume/gas/mist/vapors/spray.**
(c) Description of Hazards: N/A
(d) Unknown Acute Toxicity: N/A

Section 3 – Composition / Information on Ingredients

<table>
<thead>
<tr>
<th>(a) Chemical Name</th>
<th>(b) Common Name / Synonym</th>
<th>% Composition or other measure</th>
<th>(c) CAS No.</th>
<th>(d) Impurities / Stabilizing Additives</th>
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</thead>
<tbody>
<tr>
<td>Sodium Nitroprusside Dihydrate</td>
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<td>2.5% by weight</td>
<td>13755-38-9</td>
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</table>

Section 4 - First Aid Measures

Eye Exposure: Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Skin Exposure: Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Ingestion: Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Antidotal treatment of cyanide toxicity consists of providing a buffer for cyanide by using sodium nitrite to convert as much hemoglobin into methemoglobin as the person can safely tolerate; and then infusing sodium thiosulfate in sufficient quantity to convert the cyanide into thiocyanate. The necessary medications for treating cyanide toxicity are contained in commercially available Cyanide Antidote Kits. Cyanide Antidote Kits contain both amyl nitrite and sodium nitrite for induction of methemoglobinemia. The amyl nitrite is supplied in the form of inhalant ampules, for administration in environments where intravenous administration of sodium nitrite may be delayed. In a patient who already has a patent intravenous line, use of amyl nitrite confers no benefit that is not provided by infusion of sodium nitrite. Sodium nitrite is available in a 3% solution, and 4-6 mg/kg (about 0.2 mL/kg) should be injected over 2-4 minutes. This dose can be expected to convert about 10% of the patient’s hemoglobin into methemoglobin;
this level of methemoglobinemia is not associated with any important hazard of its own. The nitrite infusion may cause transient vasodilatation and hypotension, and this hypotension must, if it occurs, be routinely managed. Immediately after infusion of the sodium nitrite, sodium thiosulfate should be infused. This agent is available in 10% and 25% solutions, and the recommended dose is 150-200 mg/kg; a typical adult dose is 50 mL of the 25% solution. Thiosulfate treatment of an acutely cyanide-toxic patient will raise thiocyanate levels, but not to a dangerous degree. The nitrite/thiosulfate regimen may be repeated, at half the original doses, after two hours. Hemodialysis is ineffective in removal of cyanide, but it will eliminate most thiocyanate

Injection: N/A

Inhalation: Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Notes to Physician: See patient package insert in shipping carton for complete information.

Section 5 –Fire-fighting Measures

(a) Extinguishing Media As with any fire, use extinguishing media appropriate for primary cause of fire.

(b) Hazardous Combustion Products: None anticipated for this aqueous product.

(c) Special Protective Equipment / Precautions: No special provisions required beyond normal firefighting equipment. As with all fires, evacuate personnel to a safe area. Fire fighters should wear self-contained breathing apparatus to avoid inhalation of smoke. Product is aqueous-based and is not expected to present a fire hazard concern.

Section 6 - Accidental Release Measures

Spill: Isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill procedures. Absorb the liquid with suitable material and clean affected area with soap and water. Dispose of spill materials according to the applicable federal, state, or local regulations.

Release to Air: N/A
Release to Water: N/A

**Section 7 - Handling and Storage**

**General Handling:** No special handling required for hazard control under conditions of normal product use.

**Storage Conditions:** No special storage required for hazard control. Protect from light. For product protection, follow storage recommendations noted on the product case label, the primary container label, or the product insert.

**Section 8 - Exposure Controls / Personal Protection**

(a) **Exposure Limits**

<table>
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<tr>
<th>Compound</th>
<th>Issuer</th>
<th>Type</th>
<th>Exposure Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium Nitroprusside</td>
<td>OSHA</td>
<td>PEL</td>
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<tr>
<td></td>
<td>ACGIH</td>
<td>TLV</td>
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</table>

(b) **Engineering Controls**

Ventilation: N/A

(c) **Individual Protection Measures**

Respiratory Protection: Respiratory protection is normally not needed during intended product use. However, if the generation of aerosols is likely, and engineering controls are not considered adequate to control potential airborne exposures, the use of an approved air-purifying respirator with a HEPA cartridge (N95 or equivalent) is recommended under conditions where airborne aerosol concentrations are not expected to be excessive. For uncontrolled release events, or if exposure levels are not known, provide respirators that offer a high protection factor such as a powered air purifying respirator or supplied air. A respiratory protection program that meets OSHA's 29 CFR 1910.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions require respirator use. Personnel who wear respirators should be fit tested and approved for respirator use as required.
### Sodium Nitroprusside Injection  
**Safety Data Sheet (SDS)**

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<th>SDS Issue Date:</th>
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<td>R-SOP-009-F001</td>
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<tr>
<td>Page:</td>
<td>5 of 10</td>
</tr>
</tbody>
</table>

**Eye Protection:**  
Eye protection is normally not required during intended product use. However, if eye contact is likely to occur, the use of chemical safety goggles (as a minimum) is recommended.

**Skin Protection:**  
If skin contact with the product formulation is likely, the use of latex or nitrile gloves is recommended.

**Other Protective Equipment:**  
N/A

**Additional Exposure Precautions:**  
N/A

---

### Section 9 - Physical and Chemical Properties

<table>
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<th>(a)</th>
<th>Appearance</th>
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<td>(b)</td>
<td>Odor</td>
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<tr>
<td>(c)</td>
<td>Odor Threshold</td>
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<td>(d)</td>
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<td>(e)</td>
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<td>Upper Lower Flammability or Explosion Limits</td>
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<tr>
<td>(m)</td>
<td>Relative Density</td>
<td>N/A</td>
</tr>
<tr>
<td>(n)</td>
<td>Solubility(ies)</td>
<td>Slightly soluble in alcohol. Soluble in water</td>
</tr>
<tr>
<td>(o)</td>
<td>Partition Coefficient: n-octanol/water</td>
<td>N/A</td>
</tr>
<tr>
<td>(p)</td>
<td>Auto-ignition Temperature</td>
<td>N/A</td>
</tr>
<tr>
<td>(q)</td>
<td>Decomposition Temperature</td>
<td>N/A</td>
</tr>
<tr>
<td>(r)</td>
<td>Viscosity</td>
<td>N/A</td>
</tr>
</tbody>
</table>
### Section 10 - Stability and Reactivity

(a) **Reactivity**

Not determined.

(b) **Chemical Stability**

Stable under standard use and storage conditions. However, product is sensitive to certain wavelengths of light. Protect from light.

(c) **Possibility of Hazardous Reactions**

Not determined.

(d) **Conditions to Avoid**

Not determined.

(e) **Incompatible Materials**

Not determined. May degrade in presence of acid.

(f) **Hazardous Decomposition Products**

Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (Cox), nitrogen oxides (NOx), and hydrogen cyanide.

### Section 11 - Toxicological Information

(a) **Likely Routes of Exposure**

Ingestion, Inhalation, skin, eye

(b) **Symptoms related to the physical, chemical and toxicological characteristics**

None known from workplace exposure. In clinical use, adverse effects are generally an extension of the pharmacologic actions of sodium nitroprusside (e.g. excessive vasodilation and hypotension) may include nausea, vomiting, sweating, dizziness, restlessness, headache, palpitation and substernal distress. In clinical use, deaths attributable to sodium nitroprusside have resulted in patients following administration.

(c) **Delayed and immediate effects and also chronic effects from short and long term exposure**

Target organ effects: Based on clinical use, possible target organs include the skin, eyes, blood, central nervous system, and cardiovascular system. Sodium nitroprusside has not been tested for effects on fertility.
(d) Acute Toxicity

<table>
<thead>
<tr>
<th>Component</th>
<th>Type</th>
<th>Route</th>
<th>Species</th>
<th>Dosage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium Nitroprusside</td>
<td>LD$_{50}$</td>
<td>Oral</td>
<td>Rat</td>
<td>99 mg/ kg</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Mouse</td>
<td>61 mg/ kg</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Rabbit</td>
<td>34 mg/ kg</td>
</tr>
<tr>
<td>Sodium Nitroprusside Dihydrate</td>
<td>LD$_{50}$</td>
<td>Intravenous</td>
<td>Rabbit</td>
<td>1.8 mg/ kg</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Dog</td>
<td>5.0 mg/ kg</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Mouse</td>
<td>6.0 mg/ kg</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Rat</td>
<td>9.3 mg/ kg</td>
</tr>
</tbody>
</table>

(e) Hazardous Chemical Listings

- NTP: Not listed
- IARC: Not listed
- OSHA: Not listed

Section 12 - Ecological Information

| (a) | Ecotoxicity | N/A |
| (b) | Persistence and degradability | Not determined for product. |
| (c) | Bioaccumulative potential | Not determined for product. |
| (d) | Mobility in soil | Not determined for product. |
| (e) | Other Adverse Effects | N/A |

Section 13 - Disposal Considerations

Waste Disposal: All waste materials must be properly characterized. Further, disposal should be performed in accordance with the federal, state or local regulatory requirements.

Container Handling and Disposal: Dispose of container and unused contents in accordance with federal, state and local regulations.

Section 14 - Transport Information

<p>| (a) | UN Number | N/A |
| (b) | UN Proper Shipping Name | N/A |
| (c) | Transport Hazard Class(es) | N/A |
| (d) | Packing Group | N/A |
| (e) | Environmental Hazards | N/A |</p>
<table>
<thead>
<tr>
<th>(f)</th>
<th>Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code)</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>(g)</td>
<td>Special Precautions</td>
<td>N/A</td>
</tr>
</tbody>
</table>

DOT status: Not regulated  
IMDG Status: Not regulated  
ICAO/IATA Status: Not Regulated

**Section 15 - Regulatory Information**

Below is selected regulatory information chosen primarily for possible Sagent usage. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

**U.S. Regulations:**  
TSCA: Not listed  
CERCLA: Not listed  
SARA 302: Not listed  
SARA 313: Not listed  
RCRA Status: Not Listed

**Section 16 - Other Information**

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact:  
Sagent Pharmaceuticals, Inc.  
1901 N. Roselle Rd, Suite 700  
Schaumburg, IL 60195  
847-908-1600
Glossary: This glossary contains definitions of general terms used in SDSs. Not all of these Glossary Terms will apply to this SDS.

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH</td>
<td>American Conference of Governmental Industrial Hygienists</td>
</tr>
<tr>
<td>AICS</td>
<td>Australian Inventory of Chemical Substances</td>
</tr>
<tr>
<td>AIHA</td>
<td>American Industrial Hygiene Association</td>
</tr>
<tr>
<td>ANSI</td>
<td>American National Standards Institute</td>
</tr>
<tr>
<td>CAS Number</td>
<td>Chemical Abstract Service Registry Number</td>
</tr>
<tr>
<td>CERCLA</td>
<td>Comprehensive Environmental Response Compensation and Liability Act (of 1980)</td>
</tr>
<tr>
<td>CHAN</td>
<td>Chemical Hazard Alert Notice</td>
</tr>
<tr>
<td>CHEMTREC</td>
<td>Chemical Transportation Emergency Center</td>
</tr>
<tr>
<td>DOT</td>
<td>Department of Transportation</td>
</tr>
<tr>
<td>DSL</td>
<td>Domestic Substances List</td>
</tr>
<tr>
<td>ECHA</td>
<td>European Chemicals Agency</td>
</tr>
<tr>
<td>EINECS</td>
<td>European Inventory of Existing Commercial Chemical Substances</td>
</tr>
<tr>
<td>ELINCS</td>
<td>European List of Notified Chemical Substances</td>
</tr>
<tr>
<td>EPA</td>
<td>Environmental Protection Agency</td>
</tr>
<tr>
<td>GHS</td>
<td>Globally Harmonized System of Classification and Labelling of Chemicals</td>
</tr>
<tr>
<td>HEPA</td>
<td>High Efficiency Particulate Air (Filter)</td>
</tr>
<tr>
<td>HMIS</td>
<td>Hazardous Materials Identification System</td>
</tr>
<tr>
<td>IARC</td>
<td>International Agency for Research on Cancer</td>
</tr>
<tr>
<td>ICAO/IATA</td>
<td>International Civil Aviation Organization/International Air Transport Associ</td>
</tr>
<tr>
<td>IMO</td>
<td>International Maritime Organization</td>
</tr>
<tr>
<td>KOW</td>
<td>Octanol/Water Partition Coefficient</td>
</tr>
<tr>
<td>LEL</td>
<td>Lower Explosive Limit</td>
</tr>
<tr>
<td>MSDS</td>
<td>Material Safety Data Sheet</td>
</tr>
<tr>
<td>MSHA</td>
<td>Mine Safety and Health Administration</td>
</tr>
<tr>
<td>NA</td>
<td>Not Applicable, except in Section 14 where NA = North America</td>
</tr>
<tr>
<td>NE</td>
<td>Not Established</td>
</tr>
<tr>
<td>NADA</td>
<td>New Animal Drug Application</td>
</tr>
<tr>
<td>NAIF</td>
<td>No Applicable Information Found</td>
</tr>
<tr>
<td>NCI</td>
<td>National Cancer Institute</td>
</tr>
<tr>
<td>NDSL</td>
<td>Non-Domestic Substances List</td>
</tr>
<tr>
<td>NFPA</td>
<td>National Fire Protection Association</td>
</tr>
<tr>
<td>NIOSH</td>
<td>National Institute for Occupational Safety and Health</td>
</tr>
<tr>
<td>NPDES</td>
<td>National Pollutant Discharge Elimination System</td>
</tr>
<tr>
<td>NOS</td>
<td>Not Otherwise Specified</td>
</tr>
<tr>
<td>NTP</td>
<td>National Toxicology Program</td>
</tr>
<tr>
<td>OSHA</td>
<td>Occupational Safety and Health Administration</td>
</tr>
<tr>
<td>OEL</td>
<td>Occupational Exposure Limit</td>
</tr>
<tr>
<td>PEL</td>
<td>Permissible Exposure Limit (OSHA)</td>
</tr>
<tr>
<td>RCRA</td>
<td>Resource Conservation and Recovery Act</td>
</tr>
<tr>
<td>RQ</td>
<td>Reportable Quantity</td>
</tr>
</tbody>
</table>
RTECS | Registry of Toxic Effects of Chemical Substances
---|---
SARA | Superfund Amendments and Reauthorization Act
SDS | Safety Data Sheet
STEL | Short Term Exposure Limit
TLV | Threshold Limit Value (ACGIH)
TPQ | Threshold Planning Quantity
TSCA | Toxic Substances Control Act
TWA | Time Weighted Average/8 Hours Unless Otherwise Noted
UEL | Upper Explosive Limit
UN | United Nations
USP | United States Pharmacopeia
WEEL | Workplace Environmental Exposure Level (AIHA)
WHMIS | Workplace Hazardous Materials Information System
# SODIUM NITROPRUSSIDE Injection

<table>
<thead>
<tr>
<th></th>
<th>Individual Vial (RSS-Limited)</th>
<th>Carton of Vials (GS1-128)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>NDC #25021-310-02</strong></td>
<td><img src="barcode1" alt="Barcode" /></td>
<td><img src="barcode2" alt="Barcode" /></td>
</tr>
<tr>
<td><strong>50 mg per 2 mL</strong></td>
<td>(01)00325021310021</td>
<td>(01)00325021310021</td>
</tr>
</tbody>
</table>

[Click here for Important Product Safety Information](#)

Package Insert

Copyright © 2016 Sagent Pharmaceuticals, Inc.
Sagent Pharmaceuticals, Inc.
Wholesaler / Distributor
Return Goods Policy

Prior Authorization:

Prior authorization from Sagent Pharmaceuticals, or Sagent, in the form of a Returned Goods Authorization (RGA), is required for all product returns. Prior authorization and issuance of credit is subject to the below terms and conditions. Sagent’s only authorized return facility is located at 4580 Mendenhall Road, Memphis, TN 38141 (“Sagent Memphis”). Sagent is not responsible for product shipping cost or other charges for products returned to a facility other than Sagent Memphis.

Please contact Sagent customer service department at 866-625-1618 for RGA assistance.

Return Shipment Instructions:

Returned products must contain a packing list with customer account information and debit memo (RGA) number clearly designated. Use only one debit memo (RGA) number per return shipment. If a return shipment is multiple boxes, photocopy paperwork with debit memo (RGA) number and place in each box. It is suggested that the return be insured and records kept. Sagent is not responsible for return shipments prior to receipt by Sagent Memphis.

All pre-authorized returns, evidenced by an RGA, must be sent to the following address:

Sagent Pharmaceuticals
4580 Mendenhall Road
Memphis, TN 38141

Returnable Items:

- Product must be within six (6) months prior to and twelve (12) months post expiration.
- Product must have a VALID Sagent lot number and expiry date.
- Product must be in original, unaltered container/trade package.

Conditions for Returned Goods Credit:

- A valid Return Goods Authorization (RGA) Number must accompany all returns for proper credit.
- RGA Numbers are valid for 90 days from issuance. Expired RGA Numbers will be considered invalid and no credit will be issued.

Revised on 10/17/07
• All returned product must be received at Sagent Memphis within 90 days of RGA issuance to receive credit. Products that have been destroyed by customers or agent of customer will not receive credit.
• Partials will not be accepted.
• Product must not be damaged by fire, smoke, heat, water, acts of God or be returned as the result of bankruptcy proceedings.
• Product must not be damaged by improper handling, storage or shipping.
• Product must not require refrigeration.
• Packages must not be marked or disfigured in any way.
• Reimbursement price will be based on the lower of the customer’s original purchase price or current price.
• Sagent will issue an eighty-percent (80%) credit allowance based on the lower of the customer’s original purchase price or current price.
• Credit will be allowed toward future purchases of any Sagent products. Credits from returned goods are valid for one (1) year from the date of issuance.
• Returns totaling fifty dollars ($50.00) or less are not eligible for credit.
• Product must be returned by the customer who purchased the product from Sagent. Credit will be issued to customer’s account.
• Returned products will be verified by Sagent and the final credit will be calculated based upon Sagent’s count.

Shipping Errors/Damaged Shipments:

Products shipped in error by Sagent are subject to 100% replacement credit if reported to Sagent within ten (10) days of receipt and returned to Sagent in original condition within 25 days of receipt. Products damaged in transit are subject to 100% replacement credit if reported to Sagent within ten (10) working days of receipt and returned to Sagent within 25 days of receipt. Contact Sagent Customer Service at 866-625-1618 to report shipping errors or damaged shipments.

Return Transportation Charges:

Prepaid by customer except when return is due to shipping error or products damaged in transit.

Terms of Return Policy:

• Product(s) returned to the wholesaler/distributor by their customer(s) are not returnable to Sagent.
• Sagent will not reimburse customer costs relating to third-party returns, destruction charges, shipping costs or processing.
• All returns are subject to review by Sagent. Issuance of RGA does not guarantee credit. Credit issuance is dependent on confirmed receipt/review of return goods.
• Returns made to Sagent or its agent without prior approval, as evidenced by a Sagent RGA, will be destroyed and credit will not be issued.
• Sagent may, at its discretion, make exceptions to the returned goods policy based upon extenuating circumstances.

Revised on 10/17/07
Non-Returnable Items/no credit:

- Non-authorized products.
- Products with more than six (6) months dating.
- Opened products or products not in original containers/packaging.
- Product purchased as close-outs or other special pricing, e.g., free goods or short-dated promotions.
- Shipments received with concealed damages not reported within 10 days of receiving the shipment.
- Items not properly stored as outlined by the Prescription Drug Marketing Act.
- Private label, repackaged products or products not in the original Sagent container.
- Products discontinued for more than 12 months.
- Product for which proof of purchase cannot be verified.
- Products returned outside of this policy will not receive credit.

Product Recall:

Should a product recall or withdrawal be necessary, Sagent will compensate its customers only for the reasonable expense incurred in performing all recall services requested by Sagent.

Other:

Sagent Pharmaceutical reserves the right to impose a handling fee on all returned goods. Federal law prohibits our representatives from transporting products between accounts or picking-up returns. Sagent reserves the right to inspect all authorized returns prior to issuing credit and to destroy products deemed unfit for sale.