PART III: CONSUMER INFORMATION

Nipride®
Sodium Nitroprusside Injection

This leaflet is part III of a three-part "Product Monograph" published when Nipride® was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about Nipride®. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

- The immediate reduction of blood pressure of patients in hypertensive crises who have not responded adequately to standard treatment.
- Producing controlled hypotension (low blood pressure) in order to reduce bleeding during surgery when both the surgeon and anaesthesiologist decide it is necessary.

What it does:
Nipride® is a vasodilator that works by relaxing the muscles in your blood vessels to help them dilate (widen). This lowers blood pressure.

When it should not be used:
Nipride® should not be used if you:

- Are allergic to sodium nitroprusside;
- Are a physically poor risk patient being treated for compensatory hypertension (mechanism to correct high blood pressure);
- Have low brain circulation;
- Have anemia (a reduction of red blood cells)

If you are going to receive this drug in surgery, please tell your doctor if you:

- Have liver disease
- Have severe kidney disease
- Have hereditary vision loss (Leber's disease)
- Have vision problems caused by smoking
- Have a history of blood clot in your brain
- Have vitamin B_{12} deficiency.

What the nonmedicinal ingredient is:
Water for injection

What the medicinal ingredient is:
Sodium Nitroprusside injection

Nipride® is available as a sterile, clear, reddish-brown solution, free from visible particulates. Each 2 mL vial contains the equivalent of 50 mg sodium nitroprusside dihydrate in sterile water for injection.

What dosage forms it comes in:

Nipride® is a solution available in single-use amber glass vials in 50mg/ 2mL format (25 mg/mL), containing sodium nitroprusside, in water for injection.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

- Nipride® is only to be used as an intravenous infusion with 5% Dextrose. Not for direct injection.
- Nipride® can cause rapid decreases in blood pressure. In patients not properly monitored, these decreases can lead to irreversible injuries or death related to poor blood supply. Nipride® should be used only when available equipment and personnel allow blood pressure to be continuously monitored.
- Except when used briefly or at low infusion rates, Nipride® gives rise to important quantities of cyanide ion which can cause death.

BEFORE receiving Nipride® tell your doctor if:

- You have liver disease, kidney disease, anemia (a reduction of red blood cells), a seizure disorder, or a history of head injury or brain tumor, hypothyroidism (you do not produce enough thyroid hormone), difficulty breathing;
- You have an existing severe disease that may make you a poor candidate to undergo surgery;
- You are pregnant, plan to become pregnant or are breastfeeding;
- Geriatrics: you may experience a stronger lower blood pressure when you receive Nipride®, please tell your doctor your age.

INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with Nipride® include: medications to help lower your blood pressure (specifically, hydralazine or hexamethonium)

PROPER USE OF THIS MEDICATION

Nipride® is only given in hospital with adequate equipment and trained personnel who can monitor you frequently for changes to your blood pressure. It is only given using an infusion pump, micro-drip regulator or any similar device that would allow precise measurement of the flow rate of the intravenous.

Nipride® is only to be used as an intravenous infusion with 5% Dextrose. Nipride® is not for direct injection.

The infusion fluid used for administration of Nipride® should not be employed as a vehicle for simultaneous administration of any other drug.

Usual dose:

Your health care professionals will decide the best dose for you. Nipride® must be diluted in 500 to 1000 ml of 5% Dextrose Injection. No other diluents should be used. The diluted solution should be protected from light, using the supplied opaque sleeve, aluminum foil or other opaque materials. The infusion solution should be freshly prepared and any unused portion discarded. The freshly prepared solution for infusion has a very faint brownish tint. If it is highly coloured, it should be discarded.

Storage period from the time of reconstitution to the completion of intravenous administration should not exceed 24 hours.

As with all parenteral drug products, intravenous admixtures should be inspected visually for clarity, particulate matter, precipitate, discolouration and leakage prior to administration whenever solution and container permit. Solutions showing haziness, particulate matter, precipitate, discolouration or leakage should not be used. Discard unused portion.

Tell your health care practitioner right away if you think that your intravenous has come out of the vein, or if it becomes sore, red or swollen.

Overdose:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Seek emergency medical attention if you think you have received too much of this medicine. Symptoms of Nipride® overdose may include low blood pressure, shortness of breath, shallow breathing, nausea, vomiting, stomach pain, sweating, severe dizziness, headache, muscle twitching, fast or pounding heartbeat, restless feeling, loss of consciousness, and chest or back pain.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Along with its needed effects, a medicine may cause some unwanted effects. These are referred to as "side effects." Although not all of these side effects may occur, if they do occur they may need medical attention.

Nausea, retching, vomiting, sweating, apprehension, headache, restlessness, agitation, muscle twitching, abdominal pain, have been noted with too rapid reduction in blood pressure. However, these symptoms rapidly disappear with slowing of the rate of the infusion or temporary discontinuation of the infusion. Your doctor will decide the best rate of infusion for you.

Irritation of the injection site may occur.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Common	Feeling dizzy and faint or your blood pressure is too low.		√	
	Difficulty breathing		√	
	Swelling in the arms or legs		√	
Uncommon	Feeling an irregular heart beat.		√	
	Rash or other skin irritation.		√	
	Weakness		√	
	Chest pain		√	
	Confusion and somnolence (a strong desire for sleep)		√	
	Methemoglo-binemia, Symptoms include: Shortness of breath, blueness at mouth and finger tips, headache, fatigue dizziness and loss of consciousness		√	

This is not a complete list of side effects. For any unexpected effects while taking Nipride®, contact your doctor or pharmacist.

HOW TO STORE IT

Store at room temperature (15-30˚C), protect from light and freezing.

Protect from light, using the supplied opaque sleeve, aluminum foil, or other opaque material. It is not necessary to cover the infusion drip chamber or the tubing.

The storage period from the time of reconstitution to the completion of intravenous administration should not exceed 24 hours.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

Report Online at www.healthcanada.gc.ca/medeffect
Call toll-free telephone: 1-866-234-2345
Complete a Canada Vigilance Reporting Form and:
-Fax toll-free to 1-866-678-6789, or
-Mail to:.Canada Vigilance Program
Health Canada
Postal Locator 1908C
Ottawa ON KIA 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found by contacting the sponsor, Pfizer Canada ULC, at 1-800-643-6001.

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