IMPORTANT: PLEASE READ

PART III: CONSUMER INFORMATION

Heparin Sodium Injection USP

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

ABOUT THIS MEDICATION

What the medication is used for

Heparin Sodium Injection is indicated for:

- treatment to stop your blood from clotting in many surgical and non-surgical situations
- preventing and stopping the spread of blood clots in your veins
- preventing and stopping the spread of blood clots to your lungs
- treatment of some disorders of blood clotting
- prevention of blood clotting during surgery
- prevention and treatment of blood clots in your arteries

What it does

Heparin stops reactions that lead to the clotting of blood and the formation of clots. Once an active blood clot has developed, larger amounts of heparin can inhibit further clotting.

Peak levels of heparin are achieved 2-4 hours following intravenous administration, although there are considerable individual variations.

When it should not be used

BEFORE you use Heparin Sodium Injection, talk to your doctor if you have:

- severe reduction of blood platelets
- an uncontrollable active bleeding state (see **WARNINGS AND PRECAUTIONS)**, except when this is due to disseminated intravascular coagulation
- a hypersensitivity or allergy to this drug or to any ingredient in the formulation or component of the container. For a complete listing, see **What the important nonmedicinal ingredients are.**

This Heparin Sodium Injection formulation contains benzyl alcohol and should not be given to neonates, premature and low birth weight infants.

What the medicinal ingredient is
Heparin sodium

What the important nonmedicinal ingredients are
Sodium chloride
Benzyl alcohol as preservative

What dosage form it comes in
Heparin Sodium Injection is available as:
- 10 000 units per mL: vials of 10 000 units in 2 mL (1 mL fill) with preservative

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions
Fatal bleeding has occurred in infants and children due to medication errors in which 1 mL Heparin Sodium Injection vials were confused with 1 mL "catheter lock flush' vials.

Bleeding can occur at virtually any site in patients receiving heparin.

Increased resistance to heparin is frequently encountered in fever, blood clot, vein inflammation associated with a blood clot, infection with blood clotting tendencies, heart attack, cancer and in patients after surgery.

Heparin sodium should be used with extreme caution in disease states in which there is increased danger of bleeding. Some of the conditions in which increased danger bleeding exists are:
- Infections of the heart and heart valves. Severe high blood pressure.
- During and immediately following (a) spinal tap, spinal or epidural anesthesia or (b) major surgery, especially involving the brain, spinal cord, or eye.
- Conditions associated with increased bleeding tendencies, such as hemophilia, thrombocytopenia (low platelets) and some vascular purpuras.
- Ulcers of the stomach and continuous tube drainage of the stomach or small intestine.
- Menstruation, liver disease with impaired blood clotting.

Heparin sodium should be used with caution in patients at risk of increased potassium levels.

Excessive administration of potassium-free solutions may result in significant low concentrations of potassium in the blood.

Heparin is not intended for Intramuscular Use.

Allergic reaction to this drug might happen, stop the medication and consult your doctor.

Platelet count should be tested and monitored.

This Heparin Sodium Injection formulation contains benzyl alcohol and should be given with caution to pregnant and nursing women.

INTERACTIONS WITH THIS MEDICATION

Certain medications may intensify the anticoagulant effect (e.g., blood thinning effect) of Heparin Sodium Injection. Therefore, it is important for you to advise your doctor if you are taking any medications such as the following:

- other drugs used to reduce blood clotting including warfarin, dextran, alteplase or streptokinase
- acetylsalicylic acid (Aspirin)
- non-steroidal anti-inflammatory drugs (NSAIDs); drugs used to treat painful and/or inflammatory conditions of muscles or joints including ibuprofen, celecoxib or indomethacin
- hydroxychloroquine; drug used to treat malaria

PROPER USE OF THIS MEDICATION

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.

Usual dose

The product should be administered under the supervision of a qualified health professional who is experienced in the use of anticoagulant agents and in the management of patients with venous thrombosis, pulmonary embolism, acute and chronic consumptive coagulopathies and peripheral arterial embolism. Appropriate management of therapy and complications is only possible when adequate diagnostic and treatment facilities are readily available.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Side effects may include:

- irritation at the injection site
- mild pain at the injection site
- bruising at the injection site
- chills
- fever
- skin rash
- asthma
- runny nose
- tearing from eyes

- headache
- nausea
- vomiting

If the above symptoms become bothersome consult your doctor.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
COMMON Hemorrhage; bleeding			√
Thrombocytopenia; low levels of platelets in the blood			√
Osteoporosis after prolonged treatment		√	
RARE Allergic reactions			√

This is not a complete list of side effects. For any unexpected effects while taking Heparin Sodium Injection, contact your doctor or pharmacist immediately.

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 at 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, Ontario
K1A 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 at: http://www.pfizer.ca or by contacting the sponsor, Pfizer Canada ULC, at: 1-800-463-6001.

This leaflet was prepared by Pfizer Canada ULC
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