

**PART III : CONSUMER INFORMATION**

**Pr: innohep®  
(tinzaparin sodium)**

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

- an injury or surgery on the brain, spinal cord, eyes or ears
- an artificial heart valve
- a spinal/epidural anaesthesia and need high doses of innohep® as this increases the risk of bleeding

The multi-dose vials of innohep® contain benzyl alcohol and must not be given to children < 3yrs, premature infants or newborns due to the risk of developing gasping syndrome

**What the medicinal ingredient is:**

Tinzaparin sodium (a low molecular weight heparin)

**What the important non-medicinal ingredients are:**

The graduated syringes contain sodium metabisulphite. The multi-dose vials contain benzyl alcohol and sodium metabisulphite.

**What dosage forms it comes in:**

**Pre-filled single-use safety syringes:**

10,000 anti-Xa IU /mL		
2,500 IU/0.25 mL	3,500 IU/0.35 mL	4,500 IU/0.45 mL
20,000 anti-Xa IU/mL		
8,000 IU/0.4 mL	12,000 IU/0.6 mL	16,000 IU/0.8 mL
10,000 IU/0.5 mL	14,000 IU/0.7 mL	18,000 IU/0.9 mL

**Multi-dose vials:** 20,000 IU/2mL and 40,000 IU/2mL

Syringes have a 27-gauge (10,000 anti-Xa IU/mL and 20,000 anti-Xa IU/mL) or 29-gauge (20,000 anti-Xa IU/mL only),, ½ inch needle. All innohep® syringes and vials are latex-free.

**WARNINGS AND PRECAUTIONS**

- innohep® should not be given by intramuscular injection.

**ABOUT THIS MEDICATION**

**What the medication is used for:**

- to prevent the formation of blood clots (venous thromboembolism) which can form as a complication of orthopaedic or general surgery and,
- to prevent and treat clots that have blocked a blood vessel (deep vein thrombosis) or that have formed in the lungs (pulmonary embolism) and,
- to prevent bloods clots forming in dialysis lines

**What it does:**

innohep® works to prevent blood clots from forming in the blood vessels of patients at risk and is used to treat existing clots.

**When it should not be used:**

Do not use innohep® if you have or have had any of the following:

- an allergy to innohep® or its ingredients (e.g. benzyl alcohol, sodium metabisulphite) or to other LMWHs and/or heparin
- a history of decreased platelet count
- a bacterial infection of the heart (bacterial endocarditis)
- serious bleeding, or have conditions or diseases with a high risk of bleeding
- a blood clotting disorder which increases your risk of bleeding
- a cerebrovascular accident (e.g. stroke)
- a stomach or intestinal ulcer or an ulcerating cancer
- uncontrolled, severe high blood pressure
- eye disorders due to diabetes or bleeding

- Do not take other medications by intramuscular injection while you are taking innohep®.
- Benzyl alcohol may cross the placenta, therefore innohep® multi-dose vials should not be used in pregnant women.
- The sodium metabisulphite in innohep® can cause severe allergic reaction in asthmatics or those with sulphite sensitivity.
- innohep® should be used with caution in patients with poor renal function

**BEFORE you use innohep® talk to your doctor or pharmacist if you:**

- have liver or kidney disease. Elderly patients should have their kidney function checked by the doctor.
- have stomach or intestinal ulcers or have diabetes
- are asthmatic or have a sensitivity to sulphites
- have or have had serious bleeding, have a medical condition with a risk of bleeding or have low platelet levels
- have high blood pressure or had a stroke
- are pregnant, nursing or planning on becoming pregnant
- have a prosthetic heart valve
- if you need to consult with another doctor or see your dentist, be absolutely sure to tell them that you are being treated with innohep®

**INTERACTIONS WITH THIS MEDICATION**

innohep® should be used with caution if you are taking any medication that may cause increased risk of bleeding such as oral anticoagulants, NSAIDS incl. ASA, platelet inhibitors, thrombolytic agents vitamin K antagonists, activated protein C, direct factor Xa and IIa inhibitors.

Tell your doctor about all the drugs you are taking, including non prescription medicines. Do not take any drugs other than those prescribed by your doctor while you are taking innohep®

**PROPER USE OF THIS MEDICATION**

innohep® should be injected just under the surface of the skin i.e. subcutaneously (with the exception of dialysis).

Hip and Knee Surgery: A subcutaneous injection is given after surgery, once a day for 7 to 10 days. You may also receive an injection 2 hours before surgery.

General Surgery: A subcutaneous injection is given 2 hours before surgery followed by an injection once daily after surgery for 7 to 10 days.

To Treat Blood Clots: A treatment (175 anti-Xa IU/kg) dose is given once daily usually for 5 to 7 days. In some cases, longer treatment is needed. Treatment may last for 3 to 6 months. Follow the treatment period prescribed by your doctor. At the same time, you may be given a blood thinner (pill). Take both medicines as instructed.

For Hemodialysis: A single dose is delivered into the dialyser tubing at the beginning of a dialysis session. Doses in subsequent dialysis sessions are adjusted as necessary. If you are at risk for bleeding, dialysis is done using halved doses.

**At home:** Follow the instructions of your doctor or nurse carefully. Only take the prescribed dose of innohep® for the time period specified by your doctor.

**Preparing the Dose (use clean hands):**

Graduated syringes: Before using this syringe, you may need to adjust the volume to the amount prescribed by your doctor. To adjust the dose, hold the syringe with the needle pointing up and gently tap the syringe to move the air bubble to the top of the syringe. Remove the cap. Slowly push the syringe plunger up to push the air bubble out. Continue to slowly push the plunger up until the top edge of the rubber stopper reaches the line matching your dose. Follow “self-injection” instructions below.

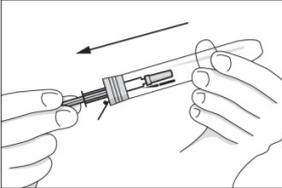
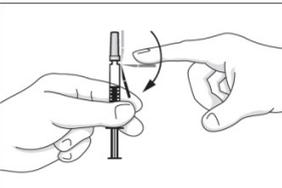
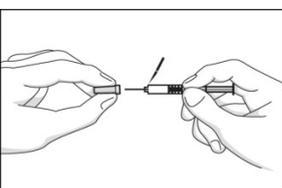
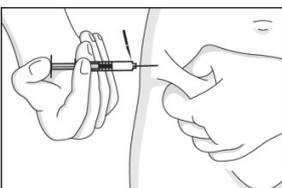
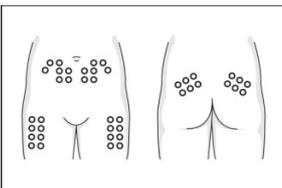
If you don’t need to adjust the dose, it is not necessary to remove the air bubble in the syringe before injecting. Follow the “self-injection” instructions below.

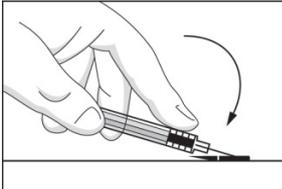
Multi-dose vials: Using a 1 mL syringe with a 27 or 29 gauge, 1/2 inch needle, insert the needle into the vial. Turn the vial upside down and pull back slowly on the plunger to draw up the desired dose. Draw up more if you see an air bubble in the syringe. Tap the syringe lightly and carefully remove air bubbles with a gentle push on the plunger. Check that you have the correct dose. If necessary, re-cap needle until ready for use.

**Instructions for Self-injection:**

A proper injection technique will help prevent pain and bruising at the injection site. Innohep® safety syringes are designed to prevent needle stick injuries. Follow these instructions carefully for proper use of the safety device.

Wash your hands before you inject the medicine. Gently wipe (do not rub) the skin around the injection site clean using an alcohol swab and let skin dry.

<p>1. Open the storage tube by flipping the tab back and bending the coloured lid all the way back. Remove the syringe and inspect the content of the syringe before you use it. If the medicine is cloudy or has particles, do not use it but take another syringe. A clear to slightly yellow solution is fine to use.</p>	
<p>2. Before removing needle cap, bend the safety device (orange tab) down and away from the cap on the needle.</p>	
<p>3. Pull the protective needle cap straight off without bending the needle. If necessary, adjust the syringe to the dose prescribed by your doctor as previously described.</p>	
<p>4. Hold a fold of skin gently between your thumb and index finger. With the other hand gently insert the needle straight (at a right angle) into the skin fold. Be careful not to inject into the muscle. Ensure the safety device is not in the way</p>	
<p>5. Push the plunger all the way down and slowly inject the dose into the fatty tissue of the skin. The preferred location is to inject your lower stomach. You can also inject the sides of the thigh, the lower back or the upper</p>	

	<p>arm. Avoid the belly button area.</p> <p>Wait a few seconds for the solution to spread out. Gently remove the needle and then release the skin fold. Using a cotton swab, apply light pressure at the injection site. Choose a different injection site next time (for e.g., move from the left to the right side of the stomach).</p>
<p>6.</p>	<p>Using the edge of a hard surface bring the safety device up from underneath back to its original position against the needle. Place the safety device flat against a hard surface and press down firmly on the syringe until the needle locks «clicks» into the device.</p> 
<p>7.</p>	<p>Place the used syringe in the storage tube with the needle facing down and cap the tube or discard the syringe in a sharps container. The syringe is now safely secured. Take the tube or sharps container to the hospital or your pharmacist for disposal. Keep used syringe away from children.</p>

**Missed dose:**

If you miss a dose, do not double up. Continue with your next injection as scheduled. If you are not sure what to do, talk to your doctor or pharmacist.

**Overdose:**

Accidental overdose may result in bleeding which can not be treated at home.

**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.**

**SIDE EFFECTS AND WHAT TO DO ABOUT THEM**

Administration of innohep® may result in bleeding which can have serious or life-threatening consequences. Strokes and serious internal bleeding have been reported. Innohep® is generally well tolerated when used according to directions for use.

If you notice any of the following effects while you are being

treated with innohep®, contact your doctor promptly:

- persistent bleeding at the injection site and/or from surgical wounds
- bruising without apparent cause
- allergic reactions
- other bleeding such as a heavy nosebleed, blood in the urine, coughing or throwing up blood, or excessive bleeding from the gums while brushing your teeth.
- purplish or reddish discolouration or pain and bruising around the injection site
- dizziness, rapid heartbeat, shortness of breath. These signs could indicate you are bleeding internally

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

Symptom / effect	Stop taking drug and call your doctor or pharmacist
Rare: Major bleeding events (e.g. at a surgical site, stroke, blood in the urine.)	✓
Rare: Allergic reaction (incl. severe asthmatic episode)	✓

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

**HOW TO STORE IT**

Store at room temperature between 15 to 25 °C. Keep innohep® in a safe place out of the reach of children.

**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](http://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 0701D  
Ottawa, ON 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](http://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:

[www.leo-pharma.com/canada](http://www.leo-pharma.com/canada)

or by contacting the sponsor, LEO Pharma Inc. at: 1-800-668-7234

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