

innohep[®] (tinzaparin sodium) is indicated for:¹

- The treatment of deep vein thrombosis and/or pulmonary embolism.



Pr innohep[®] in Pregnancy
tinzaparin sodium (safety information)

Important **innohep**[®] information relating to Pregnant woman with VTE (special population)

Specialist involvement is highly recommended for anticoagulant treatment of pregnant women.

The 2 mL multi-dose vials (10,000 anti-Xa IU/mL and 20,000 anti-Xa IU/mL) contain 20 mg of benzyl alcohol as a preservative (10 mg of benzyl alcohol per mL)

- Benzyl alcohol may cause toxic and anaphylactoid reactions in infants and children up to 3 years old. Cases of fatal “Gasping Syndrome” have been reported in the literature, which occurred in premature infants and neonates when large amounts (99 - 404 mg/kg/day) of benzyl alcohol have been administered.
- Therefore the **multi-dose vials preserved with benzyl alcohol must not be used** in children <3 years old, newborn and preterm babies
- As this preservative may cross the placenta, **innohep**[®] **formulations without benzyl alcohol (syringes) should be used during pregnancy.** The use of innohep in women with abortus imminens is contraindicated

Important **innohep**[®] information relating to Pregnant woman with VTE (special population) *continued...*







- **innohep**[®] does not cross the placenta. Can be used during all trimesters of pregnancy if clinically needed
- *Teratogenic effects:* A large amount of data on pregnant women (more than 2,200 pregnancy outcomes) indicate no malformative nor fetoneonatal toxicity of **innohep**[®]
- Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity
- Pregnant women receiving anticoagulants, including **innohep**[®], are at increased risk for bleeding
 - Pregnant women receiving **innohep**[®] should be carefully monitored
 - Hemorrhage can occur at any site and may lead to death of mother and/or fetus
 - Pregnant women and women of child-bearing potential should be informed of the potential hazard to the fetus and the mother if **innohep**[®] is administered during pregnancy

Nursing Women:

- It is not known whether **innohep**[®] is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when **innohep**[®] is administered to nursing women.



Six (6) prefilled syringe sizes to help you discover the closest **innohep**[®] fit for the treatment of VTE*

	Patient body weight		DVT/PE Recommended dose: 175 anti-Xa IU/kg SC once daily†	
	(kg)	(lb)	Dose (IU)	Amount (mL)
 8,000 anti-Xa IU/0.4mL	31 – 36	68 – 80	6,000	0.3
	37 – 42	81 – 94	7,000	0.35
	43 – 48	95 – 107	8,000	0.4
 10,000 anti-Xa IU/0.5mL	49 – 53	108 – 118	9,000	0.45
	54 – 59	119 – 131	10,000	0.5
 12,000 anti-Xa IU/0.6mL	60 – 65	132 – 144	11,000	0.55
	66 – 70	145 – 155	12,000	0.6
 14,000 anti-Xa IU/0.7mL	71 – 76	156 – 168	13,000	0.65
	77 – 82	169 – 181	14,000	0.7
 16,000 anti-Xa IU/0.8mL	83 – 88	182 – 194	15,000	0.75
	89 – 93	195 – 205	16,000	0.8
 18,000 anti-Xa IU/0.9mL	94 – 99	206 – 218	17,000	0.85
	100 – 105	219 – 231	18,000	0.9

- Each syringe has a 29 gauge (G) needle



STORAGE AND STABILITY

- Should be stored at room temperature (15 to 25°C)
- Should not be refrigerated



SC: Subcutaneous; DVT: Deep vein thrombosis; PE: Pulmonary embolism; VTE: Venous thromboembolism

*Please consult the product monograph for complete dosing and administration information

† The recommended maximum daily dose for innohep[®] is 18,000 anti-Xa IU/day. Treatment with innohep[®] should be continued until therapeutic oral anticoagulant effect has been achieved (INR 2.0 to 3.0), usually within 5 days. The average duration of innohep[®] treatment is 7 days.

Clinical use:

innohep[®] cannot be used interchangeably, unit for unit, with unfractionated heparin or other low molecular weight heparins.

Close monitoring of elderly patients with low body weight (e.g., <45 kg) and those predisposed to decreased renal function is recommended.

The safety and effectiveness of **innohep**[®] in children has not been established.

Contraindications:

- Hypersensitivity to **innohep**[®] or any of its constituents
- Multi-dose vials in children <3 years old, premature infants and neonates
- History of confirmed or suspected immunologically-mediated heparin-induced thrombocytopenia or in patients in whom an in vitro platelet-aggregation test in the presence of tinzaparin is positive
- Acute or subacute septic endocarditis
- Active major haemorrhage or conditions/diseases involving an increased risk of haemorrhage
- Haemophilia or major blood clotting disorders
- Acute cerebral insults or haemorrhagic cerebrovascular accidents (except if there are systemic emboli)
- Active bleeding from a local lesion
- Uncontrolled severe hypertension
- Diabetic or haemorrhagic retinopathy
- Injury or surgery involving the brain, spinal cord, eyes or ears
- Spinal/epidural anaesthesia requiring treatment dosages of **innohep**[®] (175 IU/kg once daily)

Most serious warnings and precautions:

- **Intramuscular injection:** **innohep**[®] must not be administered by intramuscular injection due to risk of haematoma

- **Sulphite sensitivity:** Sodium metabisulphite, which may cause allergic reactions including anaphylactic symptoms and life threatening or less severe asthmatic episodes in certain susceptible people, is present in **innohep**[®] multi dose vials (10,000 and 20,000 anti-Xa IU/mL) and **innohep**[®] 20,000 anti-Xa IU/mL unit-dose graduated syringes (8,000 IU/syringe to 18,000 IU/syringe)

Other relevant warnings and precautions:

- Use in patients with prosthetic heart valves
- Patients with a history of gastro-intestinal ulceration
- Patients with severe haemodynamic instability
- Use in patients at increased risk of haemorrhage
- Use in high dose treatment of newly operated patients
- Thrombocytopenia
- Thrombocytosis
- Patients with hepatic insufficiency
- Patients at risk of hyperkalaemia
- Patients receiving spinal/epidural anaesthesia
- General surgery patients with risk factors
- Patients with severe renal impairment (CrCl <30 mL/minute)
- Pediatrics
- Geriatrics
- Patients with extreme body weight (>120 kg or <45 kg)
- Monitoring of tinzaparin levels

For more information:

Please consult the Product Monograph at www.leo-pharma.ca/innohep_pm for important information relating to adverse reactions, drug interactions, and dosing information which have not been discussed in this piece. The Product Monograph is also available through our Medical Information department at 1-800-263-4218.

REFERENCES: 1. Current **innohep**[®] Product Monograph. LEO Pharma Inc.



Pr innohep[®]
tinzaparin sodium

© 2021 LEO Pharma Inc.

innohep[®] and the LEO Lion logo are registered trademarks of LEO Pharma A/S under license and distributed by LEO Pharma Inc. Canada

www.leopharma.ca

MAT-32242