



THERAPEUTIC INDICATIONS

Inhixa is indicated in adults for:

- Prophylaxis of venous thromboembolic disease in moderate and high risk surgical patients, in particular those undergoing orthopaedic or general surgery including cancer surgery.
- Prophylaxis of venous thromboembolic disease in medical patients with an
 acute illness (such as acute heart failure, respiratory insufficiency, severe
 infections or rheumatic diseases) and reduced mobility at increased risk of
 venous thromboembolism.
- **3.** Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), excluding PE likely to require thrombolytic therapy or surgery.
- Prevention of thrombus formation in extra corporeal circulation during haemodialysis.
- **5.** Acute coronary syndrome: -Treatment of unstable angina and Non-ST-segment elevation myocardial infarction (NSTEMI), in combination with oral acetylsalicylic acid.
- Treatment of acute ST-segment elevation myocardial infarction (STEMI) including patients to be managed medically or with subsequent percutaneous coronary intervention (PCI).

This medicinal product is subject to additional monitoring.

This will allow quick identification of new safety information.

Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: https://yellowcard.mhra.gov.uk/
Adverse events should also be reported to Techdow on 01271 334609
or via email: PVUK@eu.techdow.com

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When a patient needs a dose tailored to weight, use Inhixa graduated syringes.

The medicine concentration is 100 mg/mL. Each syringe has 40 graduations.

Each graduation represents a volume of 0.025 mls:

• 0.025 mL = 2.5 mg enoxaparin

Enclosed is a dosing chart to assist in calculation of a dose.

Points to note

Never expel the air bubble before use.

Always read the instruction leaflet before use, even if you have used similar products before. The operation of Inhixa is different to other products.

If you have difficulty reading the graduations:

- Holding the grey needle shield, you can gently rotate the syringe to make the graduations more visible.
- Alternately you can rotate the plunger clockwise.
- If you still find it difficult to read the graduations, you can peel back the edge
 of the syringe label to make the graduations more visible.
 Never remove the label entirely.

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DOSING CHART

10,000 (100 mg) in 1.0 mL; 8,000 IU (80 mg) in 0.8 mL; 6,000 IU (60 mg in 0.6 mL

Each 0.025 mL graduation = 2.5 mg enoxaparin

Millilitres (mL)	Milligrams (mg)	Millilitres (mL)	Milligrams (mg)
0.025	2.5	0.525	52.5
0.050	5	0.550	55
0.075	7.5	0.575	57.5
0.1	10	0.6	60
0.125	12.5	0.625	62.5
0.150	15	0.650	65
0.175	17.5	0.675	67.5
0.2	20	0.7	70
0.225	22.5	0.725	72.5
0.250	25	0.750	75
0.275	27.5	0.775	77.5
0.3	30	0.8	80
0.325	32.5	0.825	82.5
0.350	35	0.850	85
0.375	37.5	0.875	87.5
0.4	40	0.9	90
0.425	42.5	0.925	92.5
0.450	45	0.950	95
0.475	47.5	0.975	97.5
0.5	50	1	100

ABBREVIATED PRESCRIBING INFORMATION ▼Inhixa (enoxaparin sodium) solution for injection in pre-filled syringe 2000IU (20mg) in 0.2mL; 4000IU (40mg) in 0.4mL; 6,000IU (60mg) in 0.6mL; 8000IU (80mg) in 0.8mL; 10000IU (100mg) in 1.0mL

Please refer to the Summary of Product Characteristics (SmPC) before prescribing Inhixa. Presentation: Inhixa comes in prefilled syringes of: 0.2mL contains 2000IU (20mg) enoxaparin sodium; 0.4mL contains 4000IU (40mg) enoxaparin sodium; 0.6mL contains 6000IU (60mg) enoxaparin sodium; 0.8mL contains 8000IU (80mg) enoxaparin sodium; 1.0mL contains 10000IU (100mg) enoxaparin sodium; sodium.

Indication: Prophylaxis of venous thromboembolism, particularly in orthopaedic, general or oncological surgery. Prophylaxis of venous thromboembolism in patients bedridden due to acute illnesses (40 mg/0.4mL). DVT treatment, with or without pulmonary embolism. Treatment of unstable angina and non-Q-wave myocardial infarction, in combination with acetylsalicylic acid (ASA). Acute STEMI treatment, including conservatively treated patients and percutaneous coronary angioplasty patients (60 mg/0.6 mL, 80 mg/0.8 mL, and 100 mg/1 mL). Blood clot prevention in extracorporeal circulation during haemodialysis.

Dosage and administration: For adult use. *Venous* thromboembolism (surgery): s.c. injection, 20 mg daily for 7-10 days, given 2 hours before surgery. In high-risk patients, give 40mg daily, 12 hours before surgery. Venous thromboembolism (bedridden): s.c. injection, 40 mg daily for 6-14 days. DVT: s.c. injection at either 1.5mg/kg body weight once daily for 5 days, or 1 mg/kg body weight twice daily for 5 days. In cases of thromboembolic complication, give 1 mg/kg body weight twice daily for 5 days. Oral anticoagulants should be started when appropriate. Unstable angina & non-Q-wave myocardial infarction (combined with oral ASA): s.c. injection, 1 mg/kg bw every 12 hours with oral ASA at 100mg-325mg once daily, for 2-8 days. Acute STEMI: 30 mg i.v. injection, plus 1mg/kg s.c. injection, followed by 1mg/kg s.c. injection every 12 hours, for up to 8 days. In cases of PCI, if last s.c. injection was >8 hours before balloon inflation, administer 0.3 mg/kg body weight via i.v. bolus. Bolus dosing should not be used in the elderly. Prevention of extracorporeal thrombus: 1 mg/kg body weight introduced in the intra-arterial line at start of dialysis is usually sufficient for a 4-hour session. If fibrin rings become visible, a further dose of 0.5-1 mg/kg bw may be given. In case of high risk of haemorrhage, reduce dose to 0.5 mg/kg bw for double vascular access or 0.75 mg/kg for single vascular access.

Dose adjustment is necessary in the elderly (>75 years) and in severe renal impairment (creatinine clearance < 30 ml/min): refer to SmPC.

enoxaparin, active gastric and/or duodenal ulceration, stroke (excluding apoplexy after the blockage of the arteries), increased risk of bleeding. Warnings and **Precautions:** Use caution in case of increased risk of bleeding. Exercise extreme caution in cases of heparin-induced thrombocytopenia; risk may persist for several years. Monitor platelet count. If platelets decrease by 30% or more, immediately discontinue treatment and switch to another therapy. Monitor plasma potassium in patients at risk of hyperkalaemia, particularly if treatment is >7 days. Simultaneous enoxaparin sodium and spinal/epidural anaesthesia can cause intramedullary haematoma leading to long-term or permanent paralysis. Exercise extreme caution and remove subarachnoid or epidural catheters when effect of enoxaparin is low. Monitor regularly for signs of neurological impairment. If spinal haematoma is suspected, urgent diagnosis and treatment is required. In case of PCI, minimise the risk of bleeding by adhering precisely to enoxaparin sodium dose intervals. It is important to achieve homeostasis at the puncture site after PCI. The site of the procedure should be observed for signs of bleeding or haematoma formation. Enoxaparin is not recommended in patients with prosthetic heart valves. Carefully monitor the elderly and patients with renal impairment due to a possible increased risk of bleeding complications. Carefully monitor patients with low body weight. Observe obese patients carefully for signs of thromboembolism. Measurements of APTT and ACT are unsuitable for monitoring enoxaparin activity. Risk assessment and clinical monitoring are the best indicators. Anti-Xa activity monitoring should be considered in patients with increased bleeding risk. **Interactions:** agents affecting haemostasis should be discontinued prior to enoxaparin therapy unless their use is essential. If the combination cannot be avoided, monitor carefully for blood clotting. **Pregnancy and lactation:** *Pregnancy:* There are no data in pregnant women. Do not prescribe in pregnancy unless clearly necessary. Breastfeeding: Not recommended. **Undesirable** effects: Haemorrhage, thrombocytosis, thrombocytopenia, allergic reaction, hepatic enzyme increases, urticaria, pruritis, erythema, injection site reactions including pain and haematoma have been commonly reported. Refer to the SmPC for a full list of adverse events. **Legal Category:** POM **Pack size and price:** Supplied in 10 packs, priced at: £16.69 (2000IŪ); £24.22 (4000IU); £31.41 (6000IU); £44.10 (8000IU); £57.84 (10000IU). MA Numbers: EU/1/16/1132/012; EU/1/16/1132/014; EU/1/16/1132/016; EU/1/16/1132/018; EU/1/16/1132/020. MA Holder: Techdow Europe AB, Banégatan 36, 75237 Uppsala, Sweden

Full SmPC available from Techdow Europe AB or from

Date of preparation: September 2017 ID Code: 005

Contraindications: Hypersensitivity to the active

endocarditis, severe blood coagulation disorders,

substance, heparin or its derivatives. Acute bacterial

major bleeding, thrombocytopenia in patients with a

positive in- vitro aggregation test in the presence of

Adverse events should be reported.

www.medicines.org.uk.

Reporting forms and information can be found at https://yellowcard.mhra.gov.uk/
Adverse events should also be reported to Techdow on 01271 334 609 or PVUK@eu.techdow.com

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