Abbreviated Prescribing Information

▼**Inhixa (enoxaparin sodium) solution for injection in pre-filled syringe**

Prefilled syringe available in two concentrations: 1000IU (10 mg) in 0.1 ml - 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 and 1500IU (15 mg) in 0.1 ml - 12000IU (120mg) in 0.8mL; 15000IU (150mg) in 1mL

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 and at the higher strength prefilled syringes of: 0.8mL contains 12000IU (120mg) enoxaparin sodium; 1.0mL contains 15000IU (150mg) enoxaparin sodium.

Indication: Prophylaxis of venous thromboembolism, particularly in orthopaedic, general or oncological surgery. Prophylaxis of venous thromboembolism in patients bedridden due to acute illnesses. 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. Blood clot prevention in extracorporeal circulation during haemodialysis.

Dosage and administration: Refer to SmPC prior to 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 once daily for 10 days, or 1 mg/kg twice daily for 10 days. In cases of thromboembolic complication, give 1 mg/kg 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 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 elderly patients ≥75 years of age, an initial IV bolus must not be used. Initiate dosing with 75 IU/kg (0.75 mg/kg) SC every 12 hours (maximum 7,500 IU (75 mg) for each of the first two SC doses only, followed by 75 IU/kg (0.75 mg/kg) SC dosing for the remaining doses). In cases of PCI, if last s.c. injection was >8 hours before balloon inflation, administer 0.3 mg/kg via i.v. bolus. ***Prevention of extracorporeal thrombus***: 1 mg/kg 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 may be given. In case of high risk of haemorrhage, reduce dose to 0.5 mg/kg 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.

Inhixa should not be administered IM.

The use of a tuberculin syringe or equivalent is recommended when using the multi-dose vial.

Contraindications: Hypersensitivity to the active substance, heparin or its derivatives.
Acute bacterial endocarditis, HIT, severe blood coagulation disorders, major bleeding, thrombocytopenia in patients with a positive *in-vitro* aggregation test in the presence of enoxaparin, active gastric and/or duodenal ulceration, stroke (excluding apoplexy after the blockage of the arteries), increased risk of bleeding. Newborns or premature neonates due to benzyl alcohol content **Warnings and Precautions:** Cannot be used interchangeably with other LMWHs. 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. Spinal/epidural anaesthesia or lumbar puncture must not be performed within 24 hours of administration. 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 recommended 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. Skin necrosis/cutaneous vasculitis, discontinue treatment if observed. **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:* May be used during pregnancy if the prescribing physician has established a clear need. Pregnant women should be carefully monitored for evidence of bleeding or over anticoagulation and warned of the haemorrhagic risk. Treatment should be withdrawn prior to epidural anaesthesia *Breastfeeding:* Enoxaparin can be administered during lactation **Undesirable effects:** Haemorrhage, thrombocytosis, thrombocytopenia, allergic reaction, hepatic enzyme increases, urticaria, pruritis, erythema, headache, 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: £20.86 (2000IU); £30.27 (4000IU); £39.26 (6000IU); £55.13 (8000IU); £72.30 (10000IU); £87.93 (12000IU); £99.91 (15000IU).
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; EU/1/16/1132/077; EU/1/16/1132/079,
.**Distributor:** Techdow Pharma England Ltd. Surrey Research Park Office, Surrey Technology Centre Park, 40 Occam Road, Guildford, Surrey, GU2 7YG.

Full SmPC available from Techdow Europe AB *or from* www.medicines.org.uk.

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Adverse events should be reported. 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