▼Inhixa (Enoxaparin Sodium)

PREVENTIS™ SAFETY DEVICE

PREVENTIS™ IS AN AUTOMATIC NEEDLE SHIELDING SYSTEM, WHICH HAS A COVER THAT EXTENDS OVER THE NEEDLE FOLLOWING AN INJECTION.

Prescribing Information can be found on the final slide

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.

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.

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).

Prescribing Information can be found on the final slide

Preventis™ Safety device from Beckton Dickinson

1) To perform the injection Users need to first to **push** the plunger rod to the **bottom** of the syringe => **No click**
2) **Remove** the syringe from the injection site, whilst keeping your **finger** on the **plunger rod**.
3) Then Orienting the needle away from you and others, activate BD Preventis™ by firmly **pushing** the plunger rod.
4) The protective sleeve automatically covers the needle, and an audible **click** is heard to confirm shield activation.

Your Safety is our priority

1) Each strength has a different colour Syringe and plunger to support strength differentiation
2) Each syringe incorporates an Active safety device to reduce the incidence of needle stick injury, supporting patient and healthcare professional safety

Preventis™ Safety Device
an automatic needle shielding system, with a cover that extends over the needle following an injection.
Supporting Healthcare professional Safety

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.
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.
Contraindications: Hypersensitivity to the active substance, heparin or its derivatives.
Acute bacterial endocarditis, 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. **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 (2000IU); £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 www.medicines.org.uk.

Date of preparation: September 2017 **ID Code**: 005

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.