# ABRIDGED PRODUCT INFORMATION

**C:** Enoxaparin Na

**I:** Deep vein thrombosis w/ or w/o pulmonary embolism; unstable angina & non-Q wave MI, administered concurrently w/ aspirin; acute ST-segment elevation MI including patients w/ subsequent percutaneous coronary intervention. Prophylaxis of venous thrombo-embolic diseases, in particular those which may be associated w/ orthopedic or general surgery; venous thrombo-embolism in medical patients bedridden due to acute illnesses including cardiac insufficiency, resp failure, severe infections, rheumatic diseases; prevention of thrombus formation in extracorporeal circulation during hemodialysis.

**D:** Prophylaxis of venous thrombosis in surgical patients *Patient w/ moderate risk of thromboembolism* 20 or 40 mg SC once daily. Give 1st inj 2 hr before surgical procedure. *Patient w/ high risk of thromboembolism* 40 mg SC once daily, initiated 12 hr pre-op or 30 mg bid, initiated 12-24 hr after surgery. Ave duration: 7-10 days. May continue therapy as long as there is venous thrombo-embolism risk & until patient is ambulatory eg, 40 mg once daily for 3 wk in orthopedic surgery. Prophylaxis of venous thrombo-embolism in medical patients 40 mg SC once daily for a min of 6 days & continued until return to full ambulation. Max: 14 days. DVT w/ or w/o pulmonary

embolism 1.5 mg/kg SC once daily or 1 mg/kg SC bid. *Patients w/ complicated thrombo-embolic disorders* 1 mg/kg SC bid. Ave duration: 10 days. Initiate oral anticoagulant therapy when appropriate & continue treatment until therapeutic anticoagulant effect has been achieved (INR 2-3). Prevention of extracorporeal thrombus during hemodialysis 1 mg/kg introduced into the arterial line of the circuit at the beginning of dialysis session, sufficient for a 4-hr session. Additional dose of 0.5-1 mg/kg may be given if fibrin rings are found eg, after longer sessions. *Patients w/ high risk of hemorrhage* Reduced dose to 0.5 mg/kg for double vascular access or 0.75 mg/kg for single vascular access. Unstable angina & non-Q-wave MI 1 mg/kg SC every 12 hr w/ aspirin PO (100-325 mg once daily) for min of 2 days & continued until clinical stabilization (usual duration: 2-8 days). Acute ST-segment elevation MI 30 mg single IV bolus + 1 mg/kg SC followed by 1 mg/kg SC every 12 hr. Max: 100 mg for 1st 2 doses only, followed by 1 mg/kg SC for the remaining doses. Give 15 min before & 30 min after start of fibrinolytic therapy when administered in conjunction w/ a fibrin/non-fibrin specific thrombolytic. Recommended duration: 8 days or until hospital discharge, whichever comes first. ***Elderly for the treatment of acute ST-segment elevation myocardial infarction in elderly patients ≥75 yr:*** Initially 0.75 mg/kg SC every 12 hr (max: 75 mg for 1st 2 doses only, followed by 0.75 mg/kg SC for the remaining doses). *Patients managed w/ percutaneous coronary intervention* Last enoxaparin Na SC administration given <8 hr before balloon inflation: no additional dosing needed. Last SC administration given >8 hr before balloon inflation: Administer 0.3 mg/kg IV bolus of enoxaparin Na. ***Severe renal impairment*** 1 mg/kg SC once daily. Acute STEMI in patients 75 yr 1 mg/kg SC once daily w/o initial bolus. Max: 100 mg for 1st SC dose. Acute STEMI in patients <75 yr 30 mg single IV bolus + 1 mg/kg SC, followed by 1 mg/kg SC once daily. Max: 100 mg for 1st SC dose. Prophylaxis 20 mg SC once daily.

**CI:** Hypersensitivity to enoxaparin Na, heparin or its derivatives including other LMWH.

Active major bleeding & conditions w/ a high risk of uncontrolled hemorrhage including hemorrhagic stroke.

**SP:** Concurrent use of spinal/epidural anaesth, patients w/ a history of spinal surgery or spinal deformity; history of heparin-induced thrombocytopenia w/ or w/o thrombosis. Hemorrhage; impaired hemostasis; history of peptic ulcer; recent ischemic stroke; uncontrolled severe arterial HTN; diabetic retinopathy; recent neuro- or ophth surgery. Patients w/ mechanical prosthetic heart valves. Monitor platelet counts before & during treatment; discontinue use & switch to another therapy w/ significant decrease of platelets (30-50% of initial values). Do not administer by IM route. Renal impairment. Pregnancy & lactation; pregnant women w/ mechanical prosthetic heart valves. Elderly; low-weight women (<45 kg) & low-weight men (<57 kg); obese patients.

**AR:** Haemorrhage; thrombocytosis. Thrombocytopenia. Increase hepatic enzyme. Allergic reaction; urticaria, pruritus, erythema; inj site haematoma, inj site pain, other inj site reaction.

**INT:** Discontinue use w/ agents that affect hemostasis eg, systemic salicylates, acetylsalicylic acid & NSAIDs including ketorolac, dextran 40, ticlopidine & clopidogrel, systemic glucocorticoids, thrombolytics & anticoagulants,

other antiplatelet agents including glycoprotein IIb/IIIa antagonists. If co-administration is essential, use w/ careful clinical & laboratory monitoring when appropriate.

**P/P: Inj** (pre-filled syringe) 2,000 IU/0.2 mL x 2's (P1,191) | BR-799. 4,000 IU/0.4 mL x 2's (P1,386) | BR-797. 6,000 IU/0.6 mL x 2's (P1,808) | BR-798.

Enoxaparin sodium (Clexane)
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