Clexane®Abbreviated Prescribing Information

Presentation and Forms: *Clexane® (Enoxaparin Sodium) is a Low Molecular Weight Heparin (LMWH) available in pre-filled syringes of 2000 IU (20mg)/0.2 ml, 4000 IU (40mg)/0.4ml, 6000 IU (60mg)/0.6ml and 8000 IU (80mg)/0.8ml solution for injection.* ►**Indications:** *I-Prophylaxis of venous thromboembolic disease in moderate and high risk surgical patients, in particular those undergoing orthopaedic or general surgery including cancer surgery .II-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. III- Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), excluding PE likely to require thrombolytic therapy or surgery. IV-Prevention of thrombus formation in extra corporeal circulation during haemodialysis. V- 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).* ►**Posology and method of administration:** *I-Prophylaxis of venous thromboembolism in surgical patients: -Moderate risk of thromboembolism: 2000 IU (20mg) daily, first injection 2 hours prior to surgery. -High risk of thromboembolism: 4000 IU (40mg) once daily given by SC injection preferably started 12 hours before surgery. Duration: - for patient undergo major orthopedic surgery an extended thromboprophylaxis up to 5 weeks is recommended.- for patients with high venous thromboembolism risk undergo abdominal or pelvic surgery for cancer an extended thromboprophylaxis up to 4 weeks is recommended. II–Prophylaxis of venous thromboembolism in medical patients: 4 000 IU (40 mg) once daily by SC injection . Treatment with enoxaparin sodium is prescribed for at least 6 to 14 days whatever the recovery status (e.g. mobility). The benefit is not established for a treatment longer than 14 days. III-Treatment of DVT and PE: once daily injection of 150 IU/kg (1.5 mg/kg) or as twice daily injections of 100 IU/kg (1 mg/kg). treatment is prescribed for an average period of 10 days. Oral anticoagulant therapy should be initiated when appropriate. IV- : Prevention of thrombus formation during hemodialysis : - The recommended dose is 100 IU/kg (1 mg/kg). For patients with a high risk of haemorrhage, the dose should be reduced to 50 IU/kg (0.5 mg/kg) for double vascular access or 75 IU/kg (0.75 mg/kg) for single vascular access. V-Acute coronary syndrome: treatment of unstable angina and NSTEMI and treatment of acute STEMI : -For treatment of unstable angina and NSTEMI, the recommended dose of enoxaparin sodium is 100 IU/kg (1 mg/kg) every 12 hours by SC injection administered in combination with antiplatelet therapy. Treatment should be maintained for a minimum of 2 days and continued until clinical stabilization. The usual duration of treatment is 2 to 8 days. Acetylsalicylic acid is recommended for all patients without contraindications at an initial oral loading dose of 150–300 mg (in acetylsalicylic acid-naive patients) and a maintenance dose of 75–325 mg/day long-term regardless of treatment strategy. -For treatment of acute STEMI, the recommended dose of enoxaparin sodium is a single intravenous (IV) bolus of 3 000 IU (30 mg) plus a 100 IU/kg (1 mg/kg) SC dose followed by 100 IU/kg (1 mg/kg) administered SC every 12 hours (maximum 10 000 IU (100 mg) for each of the first two SC doses). Appropriate antiplatelet therapy such as oral acetylsalicylic acid (75 mg to 325 mg once daily) should be administered concomitantly unless contraindicated. The recommended duration of treatment is 8 days or until hospital discharge, whichever comes first. When administered in conjunction with a thrombolytic (fibrin specific or non-fibrin specific), enoxaparin sodium should be given between 15 minutes before and 30 minutes after the start of fibrinolytic therapy.* ►**Contraindications**: *-Hypersensitivity to enoxaparin or heparin derivatives -History of immune mediated heparin-induced thrombocytopenia (HIT) –Active clinically significant bleeding and conditions with a high risk of haemorrhage –Spinal or epidural anaesthesia or loco-regional anaesthesia when enoxaparin sodium is used for treatment in the previous 24 hours.* ►**Warnings and Precautions**: *-General: Enoxaparin sodium cannot be used interchangeably (unit for unit) with other LMWHs. – History of HIT: Enoxaparin sodium is to be used with extreme caution in patients with a history (>100 days) of heparin-induced thrombocytopenia without circulating antibodies. – Monitoring of platelet counts– Haemorrhage: As with other anticoagulants, bleeding may occur at any site – Laboratory tests- Spinal/Epidural anaesthesia or lumbar puncture- Skin necrosis / cutaneous vasculitis- Percutaneous coronary revascularization procedures- Acute infective endocarditis- Mechanical prosthetic heart valves- Pregnant women with mechanical prosthetic heart valves- Elderly- Renal impairment- Hepatic impairment- Low weight- Obese Patients- Hyperkalaemia- : Traceability* ►**Pregnancy:** *In humans, there is no evidence that enoxaparin crosses the placental barrier during the second and third trimester of pregnancy. There is no information available concerning the first trimester. Enoxaparin sodium should be used during pregnancy only if the physician has established a clear need. Pregnant women receiving enoxaparin sodium should be carefully monitored for evidence of bleeding or excessive anticoagulation and should be warned of the haemorrhagic risk. Overall, the data suggest that there is no evidence for an increased risk of haemorrhage, thrombocytopenia or osteoporosis with respect to the risk observed in non-pregnant women, other than that observed in pregnant women with prosthetic heart valves .* ►**Breast feeding:** *It is not known whether unchanged enoxaparin is excreted in human breast milk . Clexane can be used during breastfeeding.* ►***Adverse Reactions**: -**Common:** Haemorrhage, haemorrhagic anaemia, thrombocytopenia, thrombocytosis, Allergic reactions, Headache, Hepatic enzyme increases, Urticaria, pruritus, erythema, Injection site haematoma, injection site pain, other injection site reaction.* **Uncommon:** *Hepatocellular liver injury, Bullous dermatitis, Local irritation, skin necrosis at injection site.* ***Rare:*** *Eosinophilia, Cases of immuno-allergic thrombocytopenia with thrombosis, Anaphylactic/Anaphylactoid reactions including shock, Spinal haematoma, Cholestatic liver injury, Alopecia, Cutaneous vasculitis, skin necrosis, Osteoporosis , Hyperkalaemia.* ►**Overdose:** *Accidental overdose with enoxaparin sodium after IV, extracorporeal or SC administration may lead to haemorrhagic complications. The anticoagulant effects can be largely neutralized by the slow IV injection of protamine . Revision date: June 2017*

To report an adverse event or if you have any medical enquiry, please call +964 751 740 2599 or email us at:

Levant.Pharmacovigilance@sanofi.com for adverse events

Levant.medinfo@sanofi.com for medical enquiries

Quality.Levant@sanofi.com for product technical complaints

Always refer to the full Summary of Product Characteristics (SmPC) before prescribing.

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