For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory

Abridged Prescribing Information

CLEXANE®
Enoxaparin Sodium Injection

THERAPEUTIC CATEGORY
Antithrombotic

COMPOSITION
Each prefilled syringe contains Enoxaparin 20mg / 0.2ml; 40mg / 0.4ml; 60mg / 0.6ml; 80mg / 0.8ml

THERAPEUTIC INDICATIONS
Prophylaxis of venous thromboembolic (VTE) disease in patients undergoing an orthopaedic or general surgery procedure, including cancer surgery, with a moderate or high risk of thromboembolism. Prophylaxis of VTE in medical patients bedridden due to acute illnesses, including cardiac insufficiency, respiratory failure, severe infections, rheumatic diseases. Treatment of deep vein thrombosis with or without pulmonary embolism. Prevention of thrombus formation in extra corporeal circulation during haemodialysis. Treatment of unstable angina and non-Q-wave myocardial infarction administered concurrently with aspirin. Treatment of acute ST-segment Elevation Myocardial Infarction (STEMI) including patients to be managed medically or with subsequent Percutaneous Coronary Intervention (PCI)

DOSAGE AND ADMINISTRATION
Prophylaxis of VTE in surgical patients: If moderate risk : 20 mg or 40mg sc od for 7 to 10 days. If high risk: 40 mg sc od. For patients who under major orthopaedic surgery with a high venous thromboembolic risk, thromboprophylaxis upto 5 weeks is recommended; for patients undergoing cancer surgery, upto 4 weeks is recommended
Prophylaxis of VTE in medical patients: 40 mg sc once daily for a min. of 6 days and a max. of 14 days.
Treatment of DVT with or without PE: 1.5 mg/kg sc od or 1mg/kg twice daily; average period 10 days.
Hemodialysis : 1mg / kg into arterial line.
Treatment of UA – NQWMI: 1 mg/kg sc every 12 h. with aspirin for a min of 2 days and until stabilisation.
Treatment of acute STEMI: 30mg single IV bolus plus 1mg/kg sc dose followed by 1mg/kg sc every 12h.

SAFETY-RELATED INFORMATION
Contraindications: Patients with known hypersensitivity to enoxaparin sodium, heparin or other low molecular weight heparins (LMWHs). History of immune mediated heparin-induced thrombocytopenia (HIT) within the past 100 days or in the presence of circulating antibodies. Active major bleeding and conditions with a high risk of uncontrolled haemorrhage including recent haemorrhagic stroke.
Precautions & Warnings: DO NOT ADMINISTER BY INTRAMUSCULAR ROUTE. If bleeding occurs the origin of the hemorrhage should be investigated and appropriate treatment instituted. Use with caution in conditions with increased potential for bleeding (impaired hemostasis, history of peptic ulcer, recent ischemic stroke, uncontrolled severe arterial hypertension, diabetic retinopathy, recent neuro or ophthalmologic surgery, concomitant use of medications affecting hemostasis). Isolated cases of prosthetic heart valve thrombosis have been reported. Elderly patients (especially eighty years of age and older) may be at an increased risk for bleeding complications with the therapeutic dosage ranges. Increased risk of bleeding in patients with renal impairment. Increased risk of bleeding in low weight men and women with prophylactic dosages. Obese patients are at higher risk of thromboembolism. Patients should be observed carefully for signs and symptoms of thromboembolism. Monitoring of platelet count is recommended due to risk of antibody-mediated HIT.
LMWHs should not be used interchangeably. There have been cases of neuraxial hematomas reported with the concurrent use of enoxaparin sodium and spinal / epidural anaesthesia resulting in long term or permanent paralysis. Use with caution in patients with a history of heparin induced thrombocytopenia (HIT) with or without thrombosis. To minimise the risk of bleeding following the vascular instrumentation during the treatment of unstable angina and non-Q-wave myocardial infarction and acute segment myocardial infarction, adhere precisely to the intervals recommended between Clexane Injection doses. Use of Clexane Injection for thromboprophylaxis in pregnant women with mechanical prosthetic heart valves has not been adequately studied. Pregnant women with mechanical prosthetic hearts valves may be at higher risk of thromboembolism. At higher doses, increases in aPTT and ACT may occur. Increases in aPTT and ACT are not linearly

correlated with increasing enoxaparin sodium antithrombotic activity and therefore are unsuitable and unreliable for monitoring enoxaparin sodium activity.

Pregnancy & Lactation: To be used during pregnancy only if the physician has established a clear need. Lactating mothers receiving enoxaparin sodium should be advised to avoid breast-feeding.

Adverse Reactions: Common (≥ 1/100 to <1/10) / Very common (≥ 1/10): Haemorrhage, thrombocytosis, thrombocytopenia, allergic reactions, hepatic enzymes increase (mainly transaminases), urticaria, pruritus, erythema, injection site haematoma, injection site pain, other injection site reactions. Post marketing experience (frequency not known): anaphylactic/anaphylactoid reaction including shock, headache, cases of spinal haematoma (or neuraxial haematoma) have been reported with the concurrent use of enoxapain sodium as well as spinal/epidural anaesthesia or spinal puncture, haemorrhagic anemia, cases of immuno-allergic thrombocytopenia with thrombosis, eosinophilia, Cutaneous vasculitis, skin necrosis usually occurring at the injection site, Injection site nodules, alopecia, hepatocellular and cholestatic live injury, osteoporosis following long-term therapy (> 3 months) .

For full prescribing information please contact: Sanofi India Ltd., Sanofi House, CTS No. 117-B, L&T Business Park, Saki Vihar Road, Powai 400072

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