ENOXIR®

Enoxaparin Sodium Prefilled Syringe

Pharmacologiccategory:
Anticoagulant; low molecular weight heparin
Indications:
Acute coronary syndromes, DVT prophylaxis and DVT treatment (acute)
Dossing:
Adult:
DVT prophylaxis: SubQ
Abdominal surgery: 40 mg once daily with initial dose given 2 hours prior to surgery; continue until risk of DVT has diminished. (usually 7 to 10 days)
Hip replacement surgery: 30 mg every 12 hours, with initial dose within 12 to 24 hours after surgery and every 12 hours for at least 10 days or until risk of DVT has diminished or the patient is adequately anticoagulated on warfarin.
Once-daily dosing: 40 mg once daily, with initial dose within 9 to 15 hours before surgery, and daily for at least 10 days (or up to 35 days postoperatively) or until the risk of DVT has diminished or the patient is adequately anticoagulated on warfarin.
Knee replacement surgery: 30 mg every 12 hours, with initial dose within 12 to 24 hours after surgery and every 12 hours for at least 10 days or until risk of DVT has diminished or the patient is adequately anticoagulated on warfarin.
Medical Patients with severely- restricted mobility during acute illness: 40 mg once daily; continue until risk of DVT has diminished (usually 6 to 11 days)
DVT treatment (acute): SubQ
Outpatient treatment (without pulmonary embolism):
1mg/kg/dose every 12 hours.
Inpatient treatment (with or without pulmonary embolism):
1mg/kg/ dose every 12 hours or 1.5 mg/kg once daily.
ST-elevation MI (STEMI):
Patients<75 years of age: initial 30 mg IV single bolus plus 1 mg/kg (maximum: 100 mg for the first 2 doses only) SubQ every 12 hours. The first SubQ dose should be administered with the IV bolus. Maintenance: After first 2 doses, administer 1mg/kg SubQ every 12 hours.
Patients>75 years of age: Initial: SubQ 0.75 mg/kg every 12 hours (Note: No IV bolus is administered in population); a maximum dose of 75 mg is recommended for the first 2 doses. Maintenance: after first 2 doses, administer 0.75mg/kg SubQ every 12 hours
Additional notes on STEMI treatment: Therapy may be continued for up to 8 days or until revascularization. Unless contraindicated, all patients should receive aspirin (indefinitely) and Clopidogrel. In patients receiving thrombolytics, initiate enoxaparin dosing between 15 minutes before and 30 minutes after fibrinolytic therapy.
Unstable angina or non-ST-elevation MI:
SubQ: 1 mg/kg every 12 hours in conjunction with oral aspirin therapy; continue for the duration of hospitalization (a minimum of at least 2 days) or up to 8 days.
Geriatric: subQ:
Refer to adult dosing. Increased incidence of bleeding with doses of 1.5 mg/kg/day or 1 mg/kg every 12 hours; injection-associated bleeding and serious adverse reactions are also increased in the elderly. Careful attention should be paid to elderly patients, particularly those<45 kg.
Note: Dosage alteration/adjustment may be required.
Pediatric Note:
One mg of enoxaparin is equal to 100 units of anti-Xa activity.
Contraindications:
Hypersensitivity to heparin, enoxaparin orany component of the formulation; thrombocytopenia associated with a positive in- vitro test for antiplatelet antibodies in the presence of Enoxaparin and active major bleeding
Warnings/Precautions:
-Do not administer intramuscularly.
-When visiting your dentist or other health care providers, tell them you are using this medicine.
-Spinal or epidural hematomas, including subsequent long-term or permanent paralysis, may occur with recent or anticipated neuraxial anesthesia or spinal puncture in patientsanticoagulatedwith LMWH or heparinoids. Consider risk versus benefit prior to spinal procedures; risk is increased by the use of concomitant agents which may alter hemostasis, the use of indwelling epidural catheters, a history of spinal deformity of traumatic or repeated epidural or spinal punctures. Optimal timing between neuraxial procedures and enoxaparin administration is not known.
-Patient should be observed closely for bleeding and signs and symptoms of neurological impairment if therapy is administered during or immediately following diagnostic lumbar puncture epidural anesthesia or spinal anesthesia. If neurological compromise is noted, urgent treatment is necessary.
-Avoid mixing the contents of the syringe with other medicine or infusion solutions.
-Use caution in patients with renal failure; dosage adjustment needed if CrCl< 30 ml/min.
-Monitoring parameters: platelet, occult blood, anti-Xa levels, serum creatinine are recommended. Monitoring PT and PTT is not necessary.
-Monitoring anti-Xa levels is recommendedin pregnant women receiving enoxaparin therapy.
-Discontinue therapy and consider alternative treatment if
platelets are <100000/$mm^3$and/or thrombosis develops.
-Risk of bleeding may be increased in women<45kg and men<57 kg.
-Not to be used interchangeably (unit for unit) with heparin or any other low molecular weight heparins.
Drug Interactions:
Avoid concomitant use with any of the following: Apixaban; DabigatranEtexilate; Edoxaban; Hemin; Omacetaxine; Rivaroxaban; Urokinase; Vorapaxar
Increased effect/ toxicity:
Enoxaparin may increase the levels of: The ACE inhibitors; Aliskiren; Angiotensin II receptor blockers; Anticoagulants; Canagliflozin; Collagenase (systemic); Deferasirox; Eplerenone; Ibritumab; Nintedanib; Obintuzumab; potassium salts; potassium sparing diuretics; Rivaroxaban
The level of Enoxaparin may increase by: ASA derivatives; Agents with Antiplatelet properties; Apixaban; DabigatranEtexilate; Dasatinib; Non-steroidal anti-inflammatory agents; Omega-3 Fatty acids; Pentoxifyline; Salicylates; Thrombolytic agents; Vitamin E; Vitamin E (oral)
Decreased effect may happen by Estrogen Derivatives; Progestines
Pregnancy and lactation:
Adverse events were not observed in animal reproduction studies. Low molecular weight heparin (LMWH) does not cross placenta; increased risks of fetal bleeding or teratogenic effects have not been reported.
Low amounts of LMWH have been detected in breast milk; however, because it has a low oral bioavailability, it is unlikely to cause adverse events in a nursing infant.
Storage:
Store below 30°C. Protect from light and freezing.
Keep in the orginal package.
The product is a clear, colorless to light yellow injectable solution. Avoid using if there are particles, color changing or any turbidity in solutions.
Use the solution after administration immediately.
Keep out of the reach of children.
Avoid using expired product.
Administration Note:
Enoxaparin is available in 100mg/ml concentrations. Administer by deep SubQ injection alternating between the left or right anterolateral and left or right posterolateral abdominal wall. Do not mix with other infusions or injections. In order to minimize bruising, do not rub injection site. To avoid loss of drug from the prefilled syringes, do not expel the air bubble from the syringe prior to injection.
Availability:
Each box contains: 6 or 2 prefilled syringes of Enoxaparin Sodium 4000 anti-XaIU e.q. 40 mg or 6000 anti-XaIU e.q. 60 mg or 8000 anti-XaIU e.q. 80 mg by Exirpharmaceutical Co.

References:
1. Lexicomp's drug information handbook, 25th edition, 2017, pages: 742-745

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