Enoject

Enoxaparin Sodium USP

COMPOSITION

Enoject 40: Each pre-filled syringe contains 0.4 ml sterile solution of Enoxaparin Sodium USP 40 mg equivalent to 4000 IU Anti-Xa.
Enoject 60: Each pre-filled syringe contains 0.6 ml sterile solution of Enoxaparin Sodium USP 60 mg equivalent to 6000 IU Anti-Xa.
Enoject 80: Each pre-filled syringe contains 0.8 ml sterile solution of Enoxaparin Sodium USP 80 mg equivalent to 8000 IU Anti-Xa.

PHARMACOLOGY

Enoxaparin Sodium is a low molecular weight heparin which has antithrombotic properties. It has high anti-Xa activity and low anti-IIa or anti-thrombin activity. These anticoagulant activities are mediated through anti-thrombin III (ATIII) resulting in anti-thrombotic activities in humans.

INDICATION

• Prophylaxis of deep vein thrombosis (DVT), which may lead to pulmonary embolism (PE) in patients undergoing abdominal surgery who are at risk for thromboembolic complications, in patients undergoing hip replacement surgery during and following hospitalisation, in patients undergoing knee replacement surgery and in medical patients who are at risk for thromboembolic complications due to severely restricted mobility during acute illness.
• Prevention of thrombosis in extra-corporeal circulation during haemodialysis.
• Inpatient treatment of acute deep vein thrombosis with or without pulmonary embolism (PE), when administered in conjunction with warfarin sodium and the outpatient treatment of acute deep vein thrombosis without pulmonary embolism (PE), when administered with warfarin sodium.
• Prophylaxis of ischemic complications of unstable angina and non–Q-wave myocardial infarction, when concurrently administered with aspirin.
• Treatment of Acute ST-Segment Elevation Myocardial Infarction along with aspirin.

DOSAGE AND ADMINISTRATION

Abdominal Surgery: 4000 IU (40 mg) (subcutaneously) once a day; the initial dose is given 2 hours prior to surgery. The usual duration of administration is 7-10 days.
Hip or Knee Replacement Surgery: 3000 IU (30 mg) (subcutaneously) every 12 hours; Administer the initial dose 12-24 hours after surgery, provided that hemostasis has been established. The usual duration of administration is 7-10 days. A dose of 4000 IU (40 mg) once a day subcutaneously may be considered for hip replacement surgery for up to 3 weeks. Administer the initial dose 12 (±3) hours prior to surgery.
Prevention of thrombus formation during hemodialysis: 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) (double vascular access) or 75 IU/kg (0.75 mg/kg) (single vascular access). During hemodialysis, this drug should be introduced into the arterial line of the circuit at the beginning of the dialysis session. The effect of this dose is usually sufficient for a 4-hour session. If fibrin rings are found after a longer-than-normal session, a further dose of 50 IU to 100 IU/kg (0.5 to 1 mg/kg) may be given.
Patients during Acute illness: 4000 IU (40 mg) (subcutaneously) once a day for medical patients at risk for thromboembolic complications due to severely restricted mobility during acute illness. The usual duration of administration is 6-11 days.
Treatment of Deep Vein Thrombosis with or without Pulmonary Embolism: 100 IU/kg (1 mg/kg) (subcutaneously) every 12 hours inpatients without pulmonary embolism, who can be treated at home in an outpatient setting. The recommended dose is 100 IU/kg (1 mg/kg) every 12 hours administered subcutaneously or 150 IU/kg (1.5 mg/kg) once a day administered subcutaneously at the same time every day for inpatient (hospital) treatment of patients with pulmonary embolism.
In both outpatient and inpatient (hospital) treatments, initiate warfarin sodium therapy when appropriate (usually within 72 hours of it). Continue this injection for a minimum of 5 days and until a therapeutic oral anticoagulant effect has been achieved (International Normalization Ratio 2 to 3). The average duration of administration is 7 days.
Unstable Angina and Non–Q-Wave Myocardial Infarction: 100 IU/kg (1 mg/kg) (subcutaneously) every 12 hours in conjunction with oral aspirin therapy (100 to 325 mg once daily). Treat with this injection for a minimum of 2 days and continue until clinical stabilisation. The usual duration of treatment is 2-8 days.
Treatment of Acute ST-Segment Elevation Myocardial Infarction: Recommended dose is a single intravenous bolus of 3000 IU (30 mg) plus a 100 IU/kg (1 mg/kg) subcutaneous dose followed by 100 IU/kg (1 mg/kg) (subcutaneously) every 12 hours (maximum 10000 IU or 100 mg for the first two doses only, followed by 100 IU/kg 1 mg/kg for the remaining doses). Reduce the dosage in patients ≥75 years of age. Unless contraindicated, administer aspirin to all patients as soon as they are identified as having STEMI and continue dosing with 75 to 325 mg once daily.
When administered in conjunction with a thrombolytic (fibrin specific or non–fibrin specific), administer this injection between 15 minutes before and 30 minutes after the start of fibrinolytic therapy. The usual duration of therapy is 8 days or until hospital discharge.
For patients managed with percutaneous coronary intervention (PCI), if the last subcutaneous administration was given less than 8 hours before balloon inflation, no additional dosing is needed. If the last subcutaneous administration was given more than 8 hours before balloon inflation, administer an intravenous bolus of 30 IU/kg (0.3 mg/kg).
Dose Reduction for Patients with Severe Renal Impairment (creatinine clearance <30 mL/min):
Prophylaxis in abdominal surgery, hip or knee replacement surgery, medical patients with acute illness: 3000 IU (30 mg) administered subcutaneously once daily.
Inpatient treatment of acute deep vein thrombosis with or without pulmonary embolism, when administered in conjunction with warfarin sodium: 100 IU/kg (1 mg/kg) administered subcutaneously once daily.
Outpatient treatment of acute deep vein thrombosis without pulmonary embolism, when administered in conjunction with warfarin sodium: 100 IU/kg (1 mg/kg) administered subcutaneously once daily.
Prophylaxis of ischemic complications of unstable angina and non–Q-wave myocardial infarction, when concurrently administered with aspirin: 100 IU/kg (1 mg/kg) administered subcutaneously once daily.
Treatment of acute ST-segment elevation myocardial infarction in patients <75 years of age, when administered in conjunction with aspirin: 3000 IU (30 mg) single intravenous bolus plus a 100 IU/kg (1 mg/kg) subcutaneous dose followed by 100 IU/kg (1 mg/kg) administered subcutaneously once daily.
Treatment of acute ST-segment elevation myocardial infarction in geriatric patients ≥75 years of age, when administered in conjunction with aspirin: 100 IU/kg (1 mg/kg) administered subcutaneously once daily (no initial bolus).
Although no dose adjustment is recommended in patients with creatinine clearance 30 to 50 mL/min and creatinine clearance 50 to 80 mL/min, observe these patients frequently for signs and symptoms of bleeding.

For elderly patients:
For treatment of acute ST-segment elevation myocardial infarction in geriatric patients ≥75 years of age, do not use an initial intravenous bolus. Initiate dosing with 75 IU/kg (0.75 mg/kg) subcutaneously every 12 hours (maximum 7500 IU or 75 mg for the first two doses only, followed by 75 IU/kg or 0.75 mg/kg dosing for the remaining doses). No dose adjustment is necessary for other indications in geriatric patients unless kidney function is impaired.

CONTRAINDICATION

It is contraindicated in the following cases:
• Active and major bleeding.
• History of heparin-induced thrombocytopenia (HIT) within the past 100 days or in the presence of circulating antibodies.
• Hypersensitivity to Enoxaparin Sodium.
• Hypersensitivity to heparin or pork products.
• Hypersensitivity to benzyl alcohol (for multiple-dose formulation only).

WARNING & PRECAUTION

Patients should be cautious about the following cases-
• Use Enoxaparin Sodium with extreme caution in conditions with increased risk of hemorrhagic, such as bacterial endocarditis, congenital or acquired bleeding disorders, active ulcerative and angiodysplastic gastrointestinal disease, hemorrhagic stroke or shortly after brain, spinal or ophthalmological surgery or in patients treated concomitantly with platelet inhibitors.
• To minimize the risk of bleeding following the vascular instrumentation during the treatment of unstable angina, non-Q-wave myocardial infarction and acute ST-segment elevation myocardial infarction, adhere precisely to the intervals recommended between Enoxaparin Sodium doses.
• Should be used with care in patients with a bleeding diathesis, uncontrolled arterial hypertension or a history of recent gastrointestinal ulceration, diabetic retinopathy, renal dysfunction and haemorrhage.
• May cause heparin-induced thrombocytopenia (HIT) or heparin-induced thrombocytopenia with thrombosis (HITTS). HITTS may lead to organ infarction, limb ischemia or death. Monitor thrombocytopenia of any degree closely. Be cautious about it.
• Should be discontinued if the platelet count falls below 100,000/mm³ (Thrombocytopenia).
• Cannot be used interchangeably (unit for unit) with heparin or other low molecular weight heparins.
• Use of Enoxaparin Sodium for thromboprophylaxis in pregnant women with mechanical prosthetic heart valves may result in valve thrombosis.
• Do not administer by Intramuscular route.

SIDE EFFECT

The most common side effects (>1%) are bleeding, anaemia, thrombocytopenia, elevation of serum aminotransferase, diarrhoea, nausea, ecchymosis, fever, edema, peripheral edema, dyspnea, confusion and injection site pain.

USE IN PREGNANCY & LACTATION

Based on animal data, this drug is not predicted to increase the risk of major developmental abnormalities. The estimated background risk of major birth defects and miscarriage for the indicated populations is unknown.
It is unknown whether Enoxaparin Sodium is excreted in human milk. There is no information available on the effect of this drug or its metabolites on the breastfed child or milk production.

USE IN CHILDREN AND ADOLESCENTS

Safety and effectiveness of it in children have not been established. Enoxaparin Sodium multiple-dose vials are not approved for use in neonates or infants. Serious and fatal adverse reactions including "gasping syndrome" can occur in neonates and low-birth-weight infants treated with benzyl alcohol-preserved drugs, including Enoxaparin Sodium multiple-dose vials.

DRUG INTERACTION

Drugs (anticoagulants, platelet inhibitors including acetylsalicylic acid, salicylates, NSAIDs, dipyridamole or sulfinpyrazone) may enhance the risk of haemorrhage should be discontinued before initiation of Enoxaparin Sodium therapy. If coadministration is essential, conduct close clinical and laboratory monitoring.

OVERDOSAGE

Accidental overdose with Enoxaparin Sodium after IV, extracorporeal or subcutaneous administration may lead to hemorrhagic complications. Following oral administration of even large doses, it is unlikely that Enoxaparin Sodium will be absorbed.

STORAGE

Store below 25°C temperature in a cool and dry place. Do not store in refrigerator or freezer. Keep out of the reach of children.

HOW SUPPLIED

Enoject 40: Each box contains 1 pre-filled syringe containing 0.4 ml sterile solution of Enoxaparin Sodium USP 40 mg equivalent to 4000 IU Anti-Xa, a leaflet in Alu-PVC blister and an alcohol pad.
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Enoject 80: Each box contains 1 pre-filled syringe containing 0.8 ml sterile solution of Enoxaparin Sodium USP 80 mg equivalent to 8000 IU Anti-Xa, a leaflet in Alu-PVC blister and an alcohol pad.

Manufactured by:
NIPRO JMI Pharma Ltd.
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NIPRO JMI Pharma

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