

Claxo

Enoxaparin Sodium Injection (Pre-filled Syringe)

Presentation

Each ml solution contains 10000 anti-Xa IU equivalent to 100 mg Enoxaparin Sodium USP.

Claxo 40: Each pre-filled syringe (0.4ml) contains 4000 anti-Xa IU is equivalent to 40 mg Enoxaparin Sodium USP.

Claxo 60: Each pre-filled syringe (0.6ml) contains 6000 anti-Xa IU is equivalent to 60 mg Enoxaparin Sodium USP.

Pharmacodynamic Properties

Enoxaparin is a low molecular weight heparin with a high anti-Xa activity and with a low anti-IIa or anti-thrombin activity. At doses required for the various indications, Enoxaparin does not increase bleeding time. At preventive doses, Enoxaparin causes no notable modification of activated Partial Thromboplastin Time (aPTT). It neither influences platelet aggregation nor binding of fibrinogen to platelets. Enoxaparin is primarily metabolized in the liver.

Pharmacokinetic Properties

Bioavailability: 92%

Protein binding: 80%

Metabolism: liver

Half life: 4.5 hours

Indications

Claxo (Enoxaparin) is indicated for:

- ◆ Treatment of deep vein thrombosis, with or without pulmonary embolism.
- ◆ Treatment of unstable angina and non-Q-wave myocardial infarction, administered concurrently with aspirin.
- ◆ Prevention of thrombus formation in the extra-corporal circulation during haemodialysis.
- ◆ Prophylaxis of venous thromboembolic disease (prevention of blood clot formation in the veins), in particular those which may be associated with orthopedic or general surgery.
- ◆ Prophylaxis of venous thromboembolic disease in medical patients bedridden due to acute illness, including cardiac insufficiency, respiratory failure, severe infections, rheumatic diseases.

Dosage and Administration

Adult:

Treatment of deep vein thrombosis with or without pulmonary embolism	Subcutaneous injection of 100 IU/kg twice daily for 10 days, or Subcutaneous injection of 150 IU/kg once daily for 10 days
Treatment of unstable angina and non-Q-wave myocardial infarction, administered concurrently with aspirin	Subcutaneous injection of 100 IU/kg twice daily for 2 to 8 days
Prevention of thrombus formation in the extra-corporal circulation during haemodialysis.	Recommended dose of Enoxaparin is 100 IU/kg. Patients undergoing general surgery with a moderate thromboembolism risk (e.g. abdominal surgery)- 2000 IU or 4000 IU once daily by Subcutaneous injection for 7 to 10 days. The first injection should be given 2 hour prior to surgery.
Prophylaxis of venous thromboembolic disease in surgical patients.	Patients undergoing orthopedic surgery with a high thromboembolism risk - 4000 IU once daily by Subcutaneous injection for 7 to 10 days. The first injection should be given 12 hour prior to surgery.
Prophylaxis of venous thromboembolic disease in medical patients.	Recommended dose is 4000 IU once daily by Subcutaneous injection for 6 to 14 days.

Dosage Adjustment in renal Impairment

No dosage adjustment is required in patients with moderate (creatinine clearance 30-50 ml/min) and mild (creatinine clearance 50-80 ml/min) renal impairment. But, all such patients should be observed carefully for signs and symptoms of bleeding.

For patients with severe (creatinine clearance <30 ml/min) renal impairment the dosage adjustment for Prophylactic dose is: 2000 IU once daily and Therapeutic dose is: 100 IU/kg once daily.

Elderly: No dosage adjustment is necessary, unless kidney function is impaired.

Children: Safety and effectiveness of Enoxaparin in pediatric patients have not been established.

Contraindications

Hypersensitivity to Enoxaparin, heparin or other low molecular weight heparins.

Precautions

Enoxaparin injection should not be administered by intramuscular route. Enoxaparin should be used with caution in conditions with increased potential for bleeding, such as impaired hemostasis, history of peptic ulcer, recent ischemic stroke, uncontrolled severe arterial hypertension, diabetic retinopathy, recent neuro or ophthalmologic surgery and low weight patients. It is recommended that the platelet count be measured before the initiation of the treatment and regularly thereafter during treatment.

Drug Interactions

Unless really needed, agents which may enhance the risk of hemorrhage should be discontinued prior to initiation of Enoxaparin injection therapy. These agents include medications such as: anticoagulants, platelet inhibitors including acetylsalicylic acid, salicylates, NSAIDs (including ketorolac tromethamine), dipyridamole, or sulfipyrazone. If co-administration is essential, close clinical and laboratory monitoring is needed.

Use In Pregnancy and Lactation

Pregnancy

Pregnancy category B. In humans, there is no evidence that Enoxaparin crosses the placental barrier. Enoxaparin should be used during pregnancy only if the physician has established a clear need. Enoxaparin is not recommended for use in pregnant women with prosthetic heart valves.

Lactation

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Enoxaparin injection is administered to nursing women.

Side Effects

Haemorrhage (bleeding), Thrombocytopenia, elevations of serum aminotransferase. Pain, bluish marks at injection sites to skin rash at injection sites. Cases of neuraxial hematomas with the concurrent use of Enoxaparin and spinal/epidural anesthesia or spinal puncture have resulted in varying degrees of neurologic injuries.

Over Dose

Accidental overdosage following administration of Enoxaparin may lead to hemorrhagic complications. Injected Enoxaparin may be largely neutralized by the slow IV injection of protamine sulfate (1% solution). The dose of protamine sulfate should be equal to the dose of Enoxaparin injected: 1 mg protamine sulfate should be administered to neutralize 1 mg Enoxaparin.

Storage Conditions

Keep away from light and store below 25° C, Do not freeze. Keep out of reach of children.

Commercial Pack

Claxo 40: Each box contains 1 pre-filled syringe containing 4000 anti-Xa IU is equivalent to 40 mg Enoxaparin Sodium USP (0.4 ml) in a blister pack.

Claxo 60: Each box contains 1 pre-filled syringe containing 6000 anti-Xa IU is equivalent to 60 mg Enoxaparin Sodium USP (0.6 ml) in a blister pack.

Manufactured by :

GENERAL
Pharmaceuticals Ltd.
Unit-2, Gazipur, Bangladesh



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