Parinox®

Enoxaparin Sodium BP

505

Presentation

Active ingredient: Enoxaparin Sodium BP.
Solvent: Water for injections BP.
Each ml of the solution contains: 10000 anti-Xa IU equivalent to 100 mg Enoxaparin Sodium.
Parinox®20: Each pre-filled syringe (0.2ml) contains 2000 anti-Xa IU equivalent to Enoxaparin Sodium BP 20 mg.
Parinox®40: Each pre-filled syringe (0.4ml) contains 4000 anti-Xa IU equivalent to Enoxaparin Sodium BP 40 mg.
Parinox®60: Each pre-filled syringe (0.6ml) contains 6000 anti-Xa IU equivalent to Enoxaparin Sodium BP 60 mg.
Parinox®80: Each pre-filled syringe (0.8ml) contains 8000 anti-Xa IU equivalent to Enoxaparin Sodium BP 80 mg.

Description

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.

Indications and Uses

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:

Indication	Recommended dosage schedule
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
	Note: Oral anticoagulant therapy should be initiated when appropriate and Enoxaparin treatment should be continued until a therapeutic anticoagulant effect has been achieved (INR 2 to 3)
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
	Note: It should be administered concurrently with oral Aspirin (100 to 325 mg once daily). Treatment with Enoxaparin in these patients should be prescribed for a minimum of 2 days and continued until clinical stabilization
Prevention of thrombus formation in the extra-corporal circulation during haemodialysis circulation during haemodialysis	Recommended dose of Enoxaparin is 100 IU/kg. For patients with a high risk of hemorrhage, the dose should be reduced to 50 IU/kg for double vascular access or 75 IU/kg for single vascular access
	Note: During haemodialysis, Enoxaparin should be introduced into the arterial line of the circuit at the beginning of the dialysis session. The effect of the dose is usually sufficient for a 4-hour session. However, if fibrin rings are found, a further dose of 50 to 100 IUlkg may be given
Prophylaxis of venous thromboembolic disease in surgical patients	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. 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.
	Note: Longer treatment duration may be appropriate in some patients, like therapy with 4000 IU once daily for 3 weeks following the initial therapy has been proven to be beneficial in orthropedic surgery.
Prophylaxis of venous thromboembolic disease in surgical 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.

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.

Contraindication

Hyper-sensitivity to either Enoxaparin, heparin or other low molecular weight heparins; major clotting disorders like history of thrombocytopenia, active gastro-intestinal ulcer or organic lesion likely to bleed, recent haemorrhagic vascular cerebral stroke. Although rare, cutaneous or systemic allergic reactions may occur.

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 opthalmologic surgery and low weight patients. It is recommended that the platelet count be measured befored the initiation of the treatment and regularly thereafter during treatment.
Use in pregnancy and lactation

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.

Drug Interaction

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 sulfinpyrazone. If co-administration is essential, close clinical and laboratory monitoring is needed.

Overdosage

Accidental overdosage following administration of Enoxaparin may lead to hemorrhagic complications. Injected Enoxaparin may be largely neutralized by the slow i.v. 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

Do not store above 30 °C. Do not freeze. Keep away from light and out of the reach of children.

Commercial Pack

Parinox® 20: Each box contains 1 pre-filled syringe (0.2 ml) containing 2000 anti-Xa IU equivalent to Enoxaparin Sodium BP 20 mg in a blister pack.
Parinox® 40: Each box contains 1 pre-filled syringe (0.4 ml) containing 4000 anti-Xa IU equivalent to Enoxaparin Sodium BP 40 mg in a blister pack.
Parinox® 60: Each box contains 1 pre-filled syringe (0.6 ml) containing 6000 anti-Xa IU equivalent to Enoxaparin Sodium BP 60 mg in a blister pack.
Parinox® 80: Each box contains 1 pre-filled syringe (0.8 ml) containing 8000 anti-Xa IU equivalent to Enoxaparin Sodium BP 80 mg in a blister pack.

Manufactured by
Incepta Pharmaceuticals Ltd
Savar, Dhaka, Bangladesh
® Registered Tradema

V.N.02

PR6