Composition: Active ingredient: Enoxaparin

sodium Solvent: Water for injections.

Each ml of the solution contains: 10000 anti-Xa IU equivalent to 100mg Enoxaparin sodium.

Cardinex-40: 4000 anti-Xa IU/0.4ml. Cardinex-60: 6000 anti-Xa IU/0.6ml. Cardinex-80: 8000 anti-Xa IU/0.8ml.

**Indications**: Cardinex is indicated for o Prophylaxis of venous thromboembolic disease (prevention of blood clot formation in the veins). o Prevention of thrombus formation in the extracorporal circluation during haemodialysis. o Treatment of unstable angina and non-Q-wave myocardial infarction during acute stage. o Treatment of established deep vein thrombosis with or without pulmonary embolism.

## **Dosage & administration:**

1mg (0.01ml) of enoxaparin corresponds approximately to 100 anti-Xa I.U. Enoxaparin should be injected by deep SUBCUTANEOUS ROUTE in prophylactic and curative treatment and **INTRAVASCULAR ROUTE** during haemodialysis. Do administer not by INTRAMASCULAR ROUTE.

Prophylaxis of venous thrombo-embolic disease in medical patients. The recommended dose of enoxaparin sodium is 4000 anti-Xa IU (0.4ml) once daily.

Treatment of established deep vein thrombosis with or without pulmonary embolism: A dose of 1mg/kg should be given subcutaneously every 12 hours. The duration of the treatment should not exceed a preiod of 10 days.

Treatment of unstable angina and non-Q-wave myocardial infarction: A dose of 1mg/kg should be given subcutaneously every 12 hours. The recommended treatment should be prescribed for a period of 2 to 8 days, until clinical stabilization of the patient.

Elderly: No dosage adjustment is necessary in preventive therapy.

Children: Enoxaparin is not recommended in children.

Or as directed by the registered physician.

## **Cardinex**

## **Pre-filled Syringe**

Contraindications: Hyper-sensitivity to either enoxaparin, heparin or other low molecular weight heparins; major clotting disorders : history of thrombocyto-penia, active gastro-intestinal ulcer or organic lesion likely to bleed. This medicine is generally inadvisable in the following situations: severely impaired renal function, haemorrhagic vascular cerebral stroke, uncontrolled arterial hypertension.

**Precautions**: It is recommended that the platelet count be measured before the initiation of the treatment and regularly thereafter during treatment.

Side effects: Haemorrhage (bleeding), Bluish marks at injection sites. Thrombocytopenia, severe skin rash at injection sites, risk of osteoporosis if treatment is administered over several months.

interaction Oral anticoagulant, thrombolytic drugs, acetylsalicylic acid at anti coagulant platelet doses (in the treatment of unstable angina and non-Q-wave myocardial infarction) glucocorticoids (general route)

Use in pregnancy and lactation: Enoxaparin has been assigned to pregnancy category B by the FDA. There are no controlled data in women pregnancy. It can be used in pregnancy if potential benefits outweigh the risk or as directed by the registered physician. Enoxaparin is likely to be excreted into the breast milk. A decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the benefit of the drug to the mother.

## Packing:

Cardinex-40: 1x1's prefilled syringe BP (0.4ml) in a blister pack.

Cardinex-60: 1x1's prefilled syringe BP (0.6ml) in a blister pack.

Cardinex-80: 1x1's prefilled syringe BP (0.8ml) in a blister pack.