EVAPARIN- PFS

Composition: EVAPARIN PFS 20 Each Pre-Filled Syringe contains: Enoxaparin Sodium IP 20 mg
(Porcine Derived) Water for Injections IP q.s. to 0.2 ml Water for Injections
EVAPARIN PFS 40: Each Pre-Filled Syringe contains: Enoxaparin Sodium IP .40 mg
(Porcine Derived) Water for Injections IP q.s. to 0.4 ml

ENOXAPARIN SODIUM INJECTION IP 300 mg / 3 ml Composition: Each multidose cartridge contains: Enoxaparin Sodium IP 300 mg/3 ml (Porcine derived) Benzyl Alcohol IP 1.5% w/v (Preservative) Water for Injections IP q.s. Indications Prophylaxis of Deep Vein Thrombosis {DVT), which may lead to pulmonary embolism (PE): • In patients undergoing abdominal surgery •In patients undergoing hip replacement surgery, during and following hospitalization. •In patients undergoing knee replacement surgery. •In medical patients who are at risk for thromboembolic complications due to severely restricted mobility during acute illness. Treatment of Acute Deep Vein:•The in patient treatment of acute deep vein thrombosis with or without pulmonary embolism, when administered in conjunction with warfarin sodium.• The outpatient treatment of acute deep vein thrombosis without pulmonary embolism when administered in conjunction with warfarin sodium. Contraindications • Active major bleeding • Thrombocytopenia associated with a positive invitro test for anti-platelet antibody in the presence of enoxaparin sodium • Known hypersensitivity to enoxaparin sodium (e.g., pruritus, urticaria, anaphylactic/ anaphylacloid reactions) • Known hypersensitivity to heparin or pork products.• Known hypersensitivity o benzyl alcohol. Dosage and administration: DVT prophylaxis in abdominal surgery: 40 mg SC once daily up to 12 days; DVT prophylaxis in knee replacement surgery: 30 mg SC every 12 hours usual duration of administration is 7 to 10 days; DVT prophylaxis in hip replacement surgery: 30 mg SC every 12 hours or 40 mg SC once daily usual duration of administration is 7 to 10 days; DVT prophylaxis in medical patients: 40 mg SC once daily usual duration of administration is 6 to 11 days; Inpatient treatment of acute DVT with or without pulmonary embolism: 1 mg/kg SC every 12 hours or 1.5 mg/kg SC once daily (with warfarin) average duration of administration is 7 days; Outpatient treatment of acute DVT without pulmonary embolism: 1 mg/kg SC every 12 hours (with warfarin) average duration of administration is 7 to 10 days. Method of administration: Enoxaparin must be administered by subcutaneous injection. Enoxaparin must not be administered by intramuscular injection. Enoxaparin is a clear, colorless to pale yellow sterile solution, and as with other parenteral drug products, should be inspected visually for particulate matter and discoloration prior to administration. Subcutaneous Injection Technique: The prefilled syringes are ready-to-use. The air bubble from the syringe should not be expelled before the injection. Patients should be lying down and Enoxaparin should be administered by deep SC Injection. Administration should be alternated between the left and right anterolateral and left and right posterolateral abdominal wall. The whole length of the needle should be introduced into a skin fold held between the thumb and forefinger; the skin fold should be held throughout the injection. To minimize bruising, do not rub the injection site after completion of the injection.

Warning and precautions: Spinal/Epidural Hematoma may occur in patients who are anticoagulated with low molecular weight heparins (LMWH) or heparinoids and are receiving neuraxial anesthesia or undergoing spinal puncture. These hematomas may result in long-term or permanent paralysis. Consider these risks when scheduling patients for spinal procedures. Increased risk of hemorrhage: Use with caution in patients at risk Concomitant medical conditions: Use with caution in patients with bleeding diathesis, uncontrolled arterial hypertension or history of recent gastrointestinal ulceration, diabetic retinopathy, renal dysfunction, or hemorrhage. History of heparin-induced thrombocytopenia: Use with caution Thrombocytopenia: Thrombocytopenia can occur with the administration of Enoxaparin. Monitor thrombocytopenia closely. If the platelet count falls below 100,000/mm3, enoxaparin should be discontinued. Interchangeability with other heparins: Do not exchange with heparin or other LMWHs. Pregnant women with mechanical prosthetic heart valves and their fetuses, may be at increased risk and may need more frequent monitoring and dosage adjustment. Laboratory Tests: Periodic complete blood counts, including platelet count, and stool occult blood tests are recommended during the course of treatment with Enoxaparin. Anti-Factor Xa may be used to monitor the anticoagulant effect of Enoxaparin in patients with significant renal impairment. Use in specific populations Severe Renal Impairment: Adjust dose for patients with creatinine clearance <30mL/min; Geriatric Patients: Monitor for increased risk of bleeding; Patients with mechanical heart valves: Not adequately studied; Hepatic Impairment: Use with caution; Low-Weight Patients: Observe for signs of bleeding. Pregnancy &lactation: Enoxaparin does not cross the placenta, and is not expected to result in fetal exposure to the drug. Based on animal data, enoxaparin is not predicted to increase the risk of major developmental abnormalities. Pregnant women with thromboembolic disease, including those with mechanical prosthetic heart valves and those with inherited or acquired thrombophilia, have an increased risk of other maternal complications and fetal loss regardless of the type of anticoagulant used. Pregnant women receiving enoxaparin should be carefully monitored for evidence of bleeding or excessive anticoagulation. Consideration for use of a shorter acting anticoagulant should be specifically addressed as delivery approaches. Cases of "gasping syndrome" have occurred in premature infants when large amounts of benzyl alcohol have been administered (99–405 mg/kg/day). The enoxaparin multiple-dose cartridge contains 15 mg benzyl alcohol per 1 mL as a preservative. Because benzyl alcohol may cross the placenta, Enoxaparin multiple-dose cartridge should be used with caution in pregnant women and only if clearly needed. Nursing Mothers: It is not known whether Enoxaparin is excreted in human milk. Because many drugs are excreted in human milk decision should be made whether to discontinue nursing or discontinue Enoxaparin, taking into account the importance of Enoxaparin to the mother. Adverse drug reactions: spinal/epidural hematoma, Increased Risk of Hemorrhage, Thrombocytopenia, Elevations of Serum Aminotransferases, Local Reactions (Mild local irritation, pain, hematoma, ecchymosis, and erythema), Anemia, Fever, Nausea, Edema, Ecchymosis, thrombocytosis, hyperkalemia. Most common adverse reactions: bleeding, anemia, thrombocytopenia, elevation of serum aminotransferase, diarrhea, and nausea.

(For the use of a registered medical practitioner or hospital or laboratory only)