

THROMBIFLO

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory Only

Abbreviated Prescribing information for THROMBIFLO-LOW MOLECULAR WEIGHT HEPARIN [Enoxaparin Sodium 20mg,40mg & 60mg Injection] [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Antithrombotic/Low Molecular Weight Heparin.

INDICATION: Thrombiflo 20 and 40: Prophylaxis of venous thromboembolic disease (prevention of blood clot formation in the veins), in particular after certain procedures. Prevention of thrombus formation in the extracorporeal circulation during hemodialysis. **Thrombiflo 60:** Treatment of established deep vein thrombosis. Treatment of unstable angina and non-Q-wave myocardial infarction during the acute stage, in combination with aspirin.

DOSAGE AND ADMINISTRATION: 1mg (0.01ml) of enoxaparin corresponds approximately to 100 anti-Xa I.U. Enoxaparin should be injected by deep SUBCUTANEOUS (SC) ROUTE in prophylactic and curative treatment and by INTRAVASCULAR ROUTE during hemodialysis.

Prophylaxis of venous thrombosis: 20mg to 40mg SC route once daily. Higher dose/frequency based on type of surgery/patient history. **Prevention of extra corporal thrombus during hemodialysis:** 1mg/kg; if fibrin ring is found add further dose of 0.5 to 1mg/kg. **Treatment of established deep vein thrombosis:** 1mg/kg 12 hourly for not more than 10 days. **Treatment of unstable angina and non-Q-wave myocardial infarction:** 1mg/kg 12 hourly for 2-8 days along with aspirin. In severe renal impairment (creatinine clearance <30 ml/min), dosage adjustment is required.

CONTRAINDICATION: Do not inject intramuscularly; for children; hypersensitivity to enoxaparin/heparin/low molecular weight heparins; major clotting disorders; history of thrombocytopenia; active GI ulcer or organic lesions likely to bleed; acute infectious endocarditis; severe impaired renal function; hemorrhagic vascular cerebral stroke; uncontrolled arterial hypertension.

WARNINGS & PRECAUTIONS: Exercise caution while use with NSAIDs, anticoagulants; aspirin; analgesic; anti-pyretic; dextran-40 parenteral use; glucocorticoids; patients with weight less than 40kg and 100kg; hepatic impairment; mild/moderate renal impairment; epidural/spinal anesthesia; decreased platelet counts; hemorrhagic disorders; uncontrolled hypertension; diabetic retinopathy; neuro or ophthalmologic surgery; impaired haemostasis; recent ischaemic stroke; hyperkalemia; chronic renal failure; diabetes mellitus; prosthetic heart valves surgery.

DRUG INTERACTIONS: It is having interaction with aspirin (and derivatives) at analgesic and antipyretic dose; NSAIDs, ticlopidine, dextran 40 (parenteral use), oral anticoagulant, thrombolytic drugs, glucocorticoids.

ADVERSE REACTIONS: Hemorrhage (bleeding); injection site reaction; allergic reaction; thrombocytopenia; osteoporosis (long term use); increase level in transaminases; pain, hematoma, local site irritation, hypersensitivity reactions, hypoaldosteronism, hyperkalaemia, valve thrombosis (with inadequate dosing), neuraxial hematomas, neurological injury, paralysis.

MARKETED BY:



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(Additional information is available on request)