doses of Enoxaparin Injection was employed. The incidence of bleeding complications was higher in elderly patients as well as in younger patients when Enoxaparin Injection was administered at doses of 1.5 mg/kg once a day or 1 mg/kg every 12 hours.

SIDE EFFECTS
Hemorrhage: The incidence of major hemorrhagic complications during Enoxaparin Injection therapy has been low.

Liver: Transient, asymptomatic elevations of liver transaminases to greater than three times the upper limit of normal have been uncommon.

Hypersensitivity: Thrombocytopenia, allergic reactions are rare but occur with Low molecular weight Heparin, anaphylactic reactions to unfractionated & Low molecular weight Heparin have been observed rarely.

Local Reactions: Mild local irritation, pain, hematoma, ecchymosis, and erythema may follow subcutaneous injection of Enoxaparin Injection.

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, dipyridamole, or sulfipyrazone. If co-administration is essential, conduct close clinical and laboratory monitoring.

STABILITY
Use Multi-Dose vial within 7 days of opening the vial

WARNINGS
Enoxaparin Injection is not intended for intramuscular administration. Enoxaparin Injection cannot be used intravenously with heparin or other low molecular weight heparins as they differ in manufacturing process, molecular weight, and antithrombotic properties.

PRESENTATION
10 ml Multi Dose Vial in pre-filled syringe as:

- BIO-ENOX® 20 mg
- BIO-ENOX® 40 mg
- BIO-ENOX® 60 mg
- BIO-ENOX® 80 mg

STORAGE
Store at 25°C or below. DO NOT FREEZE.

For use by a Registered Medical Practitioner or Hospital or Laboratory only

Efficacy of Enoxaparin Injection in the elderly was similar to that seen in younger patients. The incidence of bleeding complications was similar between elderly and younger patients when 30 mg every 12 hours or 40 mg once a day injection of 1% protamine sulfate. After 12 hours of the enoxaparin sodium injection, protamine administration may not be required. Particular care should be taken to avoid overdosage with protamine sulfate. Administration of protamine sulfate can cause severe hypotensive and anaphylactoid reactions. Because fatal reactions, often resembling anaphylaxis, have been reported with protamine sulfate, it should be given only when resuscitation techniques and treatment of anaphylactic shock are readily available.

CONTRAINDICATIONS
Enoxaparin is contraindicated in patients with bleeding disorders, active major bleeding, and associated with a positive test for anti-platelet antibody and platelet defects or in patients with a history of hypersensitivity to enoxaparin sodium and severe untreated hypertension. Patients with known hypersensitivity to heparins or pork products should not be treated with Enoxaparin.

PRECAUTIONS
Enoxaparin injection procedure should be observed carefully. It is recommended that the platelet count be monitored before the initiation of the treatment and regularly thereafter during treatment. Enoxaparin should be used with caution in cases of renal or hepatic insufficiency, history of peptic ulcer or any other lesions likely to bleed.

Mechanical/Prosthetic Heart Valves
Use of Enoxaparin has not been adequately studied for thromboprophylaxis in patients with mechanical prosthetic heart valves and has not been adequately studied for long-term use in this patient population. Pregnant women with mechanical prosthetic heart valves may be at higher risk for thrombocytopenia.

Renal Impairment
Patients with renal impairment (severe mean creatinine clearance < 1.4 mL/min) have not been studied.

Carcinogenesis, Mutagenesis, Impairment of Fertility
Enoxaparin was not mutagenic in in vitro tests, including the Ames test, mouse lymphoma cell forward mutation test, and human lymphocyte chromosomal aberration test, and in vivo rat bone marrow chromosomal aberration test.

Pregnancy
Animal studies have not been conducted that would suggest that Enoxaparin has teratogenic potential. Therefore, Enoxaparin should be used with caution in pregnancy.

Pediatric Use
Safety and effectiveness of Enoxaparin Injection in pediatric patients have not been established.

Nursing Mothers
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.

Geriatric Use
Efficacy of Enoxaparin Injection in the elderly was similar to that seen in younger patients. The incidence of bleeding complications was similar between elderly and younger patients when 30 mg every 12 hours or 40 mg once a day

Date: 14-12-2010

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