Intravas

Pre-filled Injection

Enoxaparin Sodium BP

Composition:
Each ml of the solution contains: 10000 anti-Xa IU equivalent to Enoxaparin Sodium 100 mg.
Intravas-40 Injection: Each pre-filled syringe (0.4ml) contains 4000 anti-Xa IU equivalent to Enoxaparin Sodium BP 40 mg.
Intravas-60 Injection: Each pre-filled syringe (0.6ml) contains 6000 anti-Xa IU equivalent to Enoxaparin Sodium BP 60 mg.
Intravas-80 Injection: Each pre-filled syringe (0.8ml) contains 8000 anti-Xa IU equivalent to Enoxaparin Sodium BP 80 mg.

Pharmacology:
Enoxaparin is a low molecular weight heparin with a high anti-Xa activity and with a low anti-lla 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:
Intravas 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, major colorectal or cancer surgery.
- Prophylaxis of venous thromboembolic disease in medical patients bedridden due to acute illness including acute heart failure, respiratory failure, severe infections & rheumatic diseases.

Dosage & Administrations:
Method of Administration:
Intravas prefilled disposable syringe is ready for immediate use. **Intravas** contains no antimicrobial agent and should be used only once and then discarded. **Intravas** should be injected by deep subcutaneous route in prophylactic and curative treatment and by intravenous route during hemodialysis. DO NOT ADMINISTER BY THE INTRAMUSCULAR ROUTE. The air bubble from the syringe should not be expelled before the injection. The subcutaneous injection should preferably be made when the patient is lying down. **Intravas** is administered alternatively between the left & right anterolateral or posterolateral abdominal wall. The whole length of the needle should be introduced vertically into a skin fold gently held between the thumb and forefinger. The skin fold should not be released until the injection is complete.

Dosage:
Prophylaxis of deep-vein thrombosis especially in surgical patients: by subcutaneous injection, *moderate risk*, 20 mg (2000 units) approx. 2 hours before surgery then 20 mg (2000 units) every 24 hours for 7–10 days; *high risk* (e.g. orthopaedic surgery), 40 mg (4000 units) 12 hours before surgery then 40 mg (4000 units) every 24 hours for 7–10 days.
Prophylaxis of deep-vein thrombosis in medical patients: by subcutaneous injection, 40 mg (4000 units) every 24 hours for at least 6 days and continued until patient ambulant (max. 14 days).
Treatment of deep-vein thrombosis or pulmonary embolism: by subcutaneous injection, 1.5 mg/kg (150 units/kg) every 24 hours, usually for at least 5 days (and until adequate oral anticoagulation established).
Treatment of acute ST-segment elevation myocardial infarction: adult under 75 years, by intravenous injection, 30 mg (3000 units) followed by subcutaneous injection, 1 mg/kg (100 units/kg), then by subcutaneous injection, 1 mg/kg every 12 hours for up to 8 days, max. 100 mg (10 000 units) for first two subcutaneous doses only; elderly over 75 years, by subcutaneous injection *only*, 750 micrograms/kg (75 units/kg) every 12 hours, max. 75 mg (7500 units) for first two doses only; patients undergoing percutaneous coronary intervention, additional dose, by intravenous injection, 300 micrograms/kg (30 units/kg) at time of procedure if last subcutaneous dose given more than 8 hours previously.
Note: When administered in conjunction with a thrombolytic, enoxaparin should be given between 15 minutes before and 30 minutes after the start of thrombolytic therapy.
Unstable angina and non-ST-segment-elevation myocardial infarction: by subcutaneous injection, 1 mg/kg (100 units/kg) every 12 hours usually for 2–8 days (minimum 2 days).
Prevention of clotting in extracorporeal circuits: The recommended dose is 1 mg/kg. For patients with a high risk of haemorrhage the dose should be reduced to 0.5 mg/kg for double vascular access or 0.75 mg/kg for singular vascular access. During haemodialysis, Enoxaparin should be introduced into the arterial line of the circuit at the beginning of the dialysis session. The effect of this dose is usually sufficient for a 4-hour session however, if fibrin rings are found, such as after a longer than normal session, a further dose of 0.5 to 1 mg/kg may be given.
Treatment of venous thromboembolism in pregnancy:
by subcutaneous injection, early pregnancy body-weight under 50 kg, 40 mg (4000 units) twice daily; body-weight 50–70 kg, 60 mg (6000 units) twice daily; body-weight 70–90 kg, 80 mg (8000 units) twice daily; body-weight over 90 kg, 100 mg (10 000 units) twice daily.

Side Effects:
Haemorrhage (bleeding), thrombocytopenia, local reactions (pain, haematoma and mild local irritation) may follow the subcutaneous injection of Enoxaparin. There have been reports of neuraxial haematomas with the concurrent use of Enoxaparin Sodium and spinal/epidural anaesthesia or spinal puncture resulting in varying degrees of neurologic injuries.

Contraindications:
Hypersensitivity 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 ophthalmologic surgery and low weight patients. It is recommended that the platelet count should be measured before the initiation of the treatment and regularly thereafter during treatment.

Drug Interactions:
It is recommended that agents, which affect haemostasis should be discontinued prior to Enoxaparin Sodium therapy unless strictly indicated. These agents include medications such as: systemic salicylates, acetylsalicylic acid and NSAID's including ketorolac; dextran 40, ticlopidine and clopidogrel; systemic glucocorticoids; thrombolytics and anticoagulants; other anti platelet agents including Glycoprotein IIb/IIIa antagonists

Use in special groups:
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. However, as a precaution, lactating mothers receiving Enoxaparin Sodium should be advised to avoid breast-feeding.
The elderly: No dose reduction is necessary in the elderly, unless kidney function is impaired.
Children: The safety and efficacy of Enoxaparin sodium in children have not been established.

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:
Intravas should be stored at or below 25°C. Do not freeze pre-filled syringes.

Packing:
Intravas-40 Injection: Each box contains 1/2 pre-filled syringe containing 4000 anti-Xa IU equivalent to Enoxaparin Sodium BP 40 mg (0.4 ml) in a blister pack.
Intravas-60 Injection: Each box contains 1/2 pre-filled syringe containing 6000 anti-Xa IU equivalent to Enoxaparin Sodium BP 60 mg (0.6 ml) in a blister pack.
Intravas-80 Injection: Each box contains 1/2 pre-filled syringe containing 8000 anti-Xa IU equivalent to Enoxaparin Sodium BP 80 mg (0.8 ml) in a blister pack.

Manufactured by:
ARISTOPHARMA LTD.
Shampur-Kadamtali I/A, Dhaka-Bangladesh

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