

Enoxaparin BSS [1]

ENOXAPARIN 100 mg/ml SANDOZ.. Presentations: 20 mg/0.2 ml. Each pre-filled syringe contains enoxaparin sodium with an anti-Xa activity of 2,000 IU (equivalent to 20 mg) in 0.2 ml of water for injections. 40 mg / 0.4 ml. Each pre-filled syringe contains enoxaparin sodium with an anti-Xa activity of 4,000 IU (equivalent to 40 mg) in 0.4 ml of water for injections. 60 mg / 0.6 ml. Each pre-filled syringe contains enoxaparin sodium with an anti-Xa activity of 6,000 IU (equivalent to 60 mg) in 0.6 ml of water for injections. 80 mg / 0.8 ml Each pre-filled syringe contains enoxaparin sodium with an anti-Xa activity of 8,000 IU (equivalent to 80 mg) in 0.8 ml of water for injections. 100 mg / 1.0 ml. Each pre-filled syringe contains enoxaparin sodium with an anti-Xa activity of 10,000 IU (equivalent to 100 mg) in 1.0 ml of water for injections.

Therapeutic indications. Prophylaxis of venous thromboembolic disease in surgical patients with moderate or high risk, particularly in those who undergo orthopedic surgery or general surgery including oncological surgery. Prophylaxis of venous thromboembolic disease in medical patients with an acute disease (such as acute heart failure, respiratory failure, severe infections or rheumatic diseases) and reduced mobility with an increased risk of venous thromboembolism. Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), excluding PE that probably requires thrombolytic treatment or surgery. Prevention of clot formation in the extracorporeal circulation circuit during hemodialysis. Acute coronary syndrome: - treatment of unstable angina and non-ST segment elevation myocardial infarction (STEMI), in combination with oral acetylsalicylic acid. - treatment of acute myocardial infarction with ST segment elevation (STEMI) including patients who are to be treated pharmacologically or undergo subsequent percutaneous coronary intervention (PCI).

Posology. Prophylaxis of venous thromboembolic disease in surgical patients with moderate or high risk. In patients at moderate risk of thromboembolism, the recommended dosage of enoxaparin sodium is 2,000 IU (20 mg) once daily via subcutaneous injection (SC). Enoxaparin sodium treatment should be maintained for a minimum period of 7-10 days regardless of recovery status (eg mobility). In patients at high risk of thromboembolism, the recommended dosage of enoxaparin sodium is 4,000 IU (40 mg) administered once daily via SC, preferably giving the first injection 12 hours before the intervention. If preoperative prophylactic initiation with enoxaparin sodium is required before 12 hours (eg high-risk patients awaiting delayed orthopedic surgery), the last injection should be given no later than 12 hours before surgery and resumed 12 hours after surgery. Prophylaxis of venous thromboembolism in medical patients. The recommended dose of enoxaparin sodium is 4,000 IU (40 mg) once daily via SC. Enoxaparin sodium treatment will be prescribed for at least 6 to 14 days. Treatment of DVT and PE. Enoxaparin sodium can be administered SC either as one injection per day of 150 IU / kg (1.5 mg / kg) or as two injections per day of 100 IU / kg (1 mg / kg). It is prescribed for an average period of 10 days. Prevention of clot formation during hemodialysis. The recommended dose is 100 IU / kg (1 mg / kg) of enoxaparin sodium. Acute coronary syndrome: treatment of unstable angina and STEMI and treatment of acute STEMI. For the treatment of unstable angina and STEMI, the recommended dose of enoxaparin sodium is 100 IU / kg (1 mg / kg) every 12 hours administered SC in combination with antiplatelet therapy. For treatment of acute STEMI, the recommended dose of enoxaparin sodium is an intravenous (IV) bolus of 3,000 IU (30 mg) plus a SC dose of 100 IU / kg (1 mg / kg) followed by a SC administration of 100 IU / mg (1mg / kg) every 12 hours (maximum 10,000 IU (100 mg) for each of the first two SC doses). The safety and efficacy of enoxaparin sodium in the pediatric population have not been established. For the treatment of acute STEMI in elderly patients >75 years, do not initially administer the IV bolus. There are limited data in patients with hepatic impairment. Enoxaparin sodium is not recommended in patients with end-stage renal disease. Enoxaparin sodium should not be administered intramuscularly. For prophylaxis of venous thromboembolic disease after surgery, treatment of DVT and PE, treatment of unstable angina and STEMI, enoxaparin sodium should be administered via SC. For acute STEMI, treatment should be started with a single bolus IV injection followed immediately by a SC injection. For the prevention of clot formation during extracorporeal circulation during hemodialysis, it is administered in the arterial line of a dialysis circuit. For acute STEMI, treatment should be started with a single bolus IV injection followed immediately by SC initiation. Contraindications: Active bleeding, history of bleeding disorders, severe renal impairment, hypersensitivity to enoxaparin sodium or any of the excipients.

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