Nadroparin Calcium
Injection Solution in Syrettes

Use :
Prophylaxis of thromboembolic disorders (particularly deep venous thrombosis and pulmonary embolism) in general and orthopedic surgery; treatment of deep venous thrombosis; prevention of clotting during hemodialysis

Pregnancy Risk Factor B :
Contraindications Hypersensitivity to nadroparin or any component of the formulation; acute infective endocarditis; hemorrhage or increased risk of hemorrhage (hemostasis disorder), except for disseminated intravascular coagulation (DIC) not induced by heparin; history of thrombocytopenia with nadroparin; organic lesions likely to bleed (active peptic ulceration); hemorrhagic cerebrovascular event; severe uncontrolled hypertension; diabetic or hemorrhagic retinopathy; injuries to or operations on the CNS, eyes, or ears. Not for I.M. administration

Warnings/Precautions :
Patients with recent or anticipated neuraxial anesthesia (epidural or spinal anesthesia) are at risk of spinal or epidural hematoma and subsequent paralysis. Consider risk versus benefit prior to neuraxial anesthesia. Risk is increased by concomitant agents which may alter hemostasis, as well as traumatic or repeated epidural or spinal puncture. Patient should be observed closely for bleeding if nadroparin is administered during or immediately following diagnostic lumbar puncture, epidural anesthesia, or spinal anesthesia.
Not to be used interchangeably (unit for unit) with heparin or any other low molecular weight heparins (LMWHs). Use with caution in patients with history of heparin-induced thrombocytopenia. Rare cases of thrombocytopenia with thrombosis have occurred. Use caution in patients with congenital or drug-induced thrombocytopenia or platelet defects. Discontinue therapy if platelets are <100,000/mm3.
Monitor patient closely for signs or symptoms of bleeding. Certain patients are at increased risk of bleeding. Risk factors include bacterial endocarditis; congenital or acquired bleeding disorders; active ulcerative or angiodysplastic GI diseases; severe uncontrolled hypertension; hemorrhagic stroke; recent brain, spinal, or ophthalmology surgery; concomitant treatment with platelet inhibitors; recent GI bleeding; thrombocytopenia or platelet defects; severe liver disease; hypertensive or diabetic retinopathy; or in patients undergoing invasive procedures. Use with caution in patients with severe hepatic or renal disease. Safety and efficacy in pediatric patients have not been established.
Heparin can cause hyperkalemia by affecting aldosterone. Similar reactions could occur with LMWHs. Monitor for hyperkalemia. Do not use when abortion is imminent or threatened.

Adverse Reactions Frequency not defined.
Dermatologic: Rash
Endocrine & metabolic: Hypoaldosteronism (causing hyperkalemia and/or hyponatremia)
Hematological: Bleeding, thrombocytopenia
Hepatic: ALT/AST increased
Local: Injection site hematoma, pain at injection site
Neuromuscular & skeletal: Osteopenic effects
Miscellaneous: Allergic reactions

Drug Interactions :
Antiplatelet drugs: Drugs which affect platelet function (eg, aspirin, NSAIDs, dipyridamole, ticlopidine, clopidogrel) may increase the risk of hemorrhage.
Thrombolytics (fibrinolytics): Increase risk of hemorrhage.
Warfarin: Risk of bleeding may be increased during concurrent therapy. Nadroparin is commonly continued during the initiation of warfarin therapy to assure anticoagulation and to protect against possible transient hypercoagulability.

Dosage S.C.: Adults:
Prophylaxis of thromboembolic disorders in general surgery: 2850 anti-Xa int. units once daily; begin 2-4 hours before surgery and continue for 7 days
Prophylaxis of thromboembolic disorders in hip replacement: 38 anti-Xa int. units/kg 12 hours before and 12 hours after surgery, followed by 38 anti-Xa int. units/kg/day up to and including day 3, then 57 anti-Xa int. units/kg/day for up to 10 days total therapy
Treatment of thromboembolic disorders: 171 anti-Xa int. units/kg/day to a maximum of 17,100 int. units; plasma anti-Xa levels should be 1.2-1.8 anti-Xa int. units/mL 3-4 hours postinjection
Patients at increased risk of bleeding: 86 anti-Xa int. units/kg twice daily; plasma anti-Xa levels should be 0.5-1.1 anti-Xa int. units/mL 3-4 hours postinjection
Prevention of clotting during hemodialysis: Single dose of 65 anti-Xa int. units/kg into arterial line at start of each dialysis session; may give additional dose if session lasts longer than 4 hours
Patients at risk of hemorrhage: Administer 50% of dose
Dosage adjustment in renal impairment: Reduced dose recommended

Dosage Forms Injection, solution, as calcium:
Nadroparin :
9500 anti-Xa int. units/mL (0.2 mL, 0.3 mL, 0.4 mL) [ungraduated prefilled syringe]
9500 anti-Xa int. units/mL (0.6 mL, 0.8 mL, 1 mL) [graduated prefilled syringe]
Nadroparin Forte: 19,000 anti-Xa int. units/mL (0.6 mL, 0.8 mL, 1 mL) [graduated prefilled syringe]

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Taj Pharmaceuticals Limited is a pharmaceutical company founded and based in India. The company manufacturers pharmaceutical formulations and API for India and other countries of world. The company was established in 1995 as an enterprise and in 2004 became a public limited company. As per Mumbai pharmaxil and Chemixil association the company manufacturers and exports to countries like Albania, Argentina, Austria, Chile and Iraq. In 1995 pharmaceuticals wing only has a schedule M certification for pharmaceuticals products manufacturing in India. Taj Pharmaceuticals established its manufacturing unit in Gujarat because of government policies in 1999 with WHO / GMP licence. The company in 2003 revived all the old manufacturing units and approached the FDA Gujarat for 4000 new pharmaceuticals drug permissions for the first time in India.

According to the Indian Trade Mark the company owns about 450 brands and 4600 generic manufacturing permissions in India. According to the export data analysis the company was the largest exporter of generic medicines to the Europe and Middle East countries. www.tajpharma.com

The company medicines are present in France, Georgia, Egypt and CIF countries.

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