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Coagurin® Injection (dalteparin sodium injection) is a sterile, low molecular weight heparin. It is available in single-dose, prefilled syringes preassembled with a needle guard device, and multiple-dose vials. With reference to the W.H.O. First International Low Molecular Weight Heparin Reference Standard, each syringe contains either 2500, 5000, 7500, 10,000, 12,500, 15,000 or 18,000 anti-Factor Xa international units (IU), equivalent to 16, 32, 48, 64, 80, 96 or 115.2 mg dalteparin sodium, respectively.

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Sodium injection
SUBCUTANEOUS (UNDER THE SKIN) INJECTION



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CLINICAL PHARMACOLOGY

Coagurin® (Dalteparin) is a low molecular weight heparin with antithrombotic properties. It acts by enhancing the inhibition of Factor Xa and thrombin by antithrombin. In man, dalteparin potentiates preferentially the inhibition of coagulation Factor Xa, while only slightly affecting the activated partial thromboplastin time (APTT).

Pharmacodynamics

Doses of Coagurin® (Dalteparin) Injection of up to 10,000 anti-Factor Xa IU administered subcutaneously as a single dose or two 5000 IU doses 12 hours apart to healthy subjects do not produce a significant change in platelet aggregation, fibrinolysis, or global clotting tests such as prothrombin time (PT), thrombin time (TT) or APTT. Subcutaneous (s.c.) administration of doses of 5000 IU twice daily of Coagurin® (Dalteparin) for seven consecutive days to patients undergoing abdominal surgery did not markedly affect APTT, Platelet Factor 4 (PF4), or lipoprotein lipase.

INDICATIONS AND USAGE

Coagurin® Injection is indicated for the prophylaxis of ischemic complications in unstable angina and non-Q-wave myocardial infarction, when concurrently administered with aspirin therapy (as described in CLINICAL TRIALS, Prophylaxis of Ischemic Complications in Unstable Angina and Non-Q-Wave Myocardial Infarction).

Coagurin® is also indicated for the prophylaxis of deep vein thrombosis (DVT), which may lead to pulmonary embolism (PE):

In patients undergoing hip replacement surgery;

In patients undergoing abdominal surgery who are at risk for thromboembolic complications;

In medical patients who are at risk for thromboembolic complications due to severely restricted mobility during acute illness.

Coagurin® is also indicated for the extended treatment of symptomatic venous thromboembolism (VTE) (proximal DVT and/or PE), to reduce the recurrence of VTE in patients with cancer.

Coagurin® (Dalteparin), an anticoagulant ("blood thinner"), to prevent harmful blood clots from forming. The drug will be injected under the skin (subcutaneously) once a day.

THIS MEDICINE IS USED TO REDUCE THE RISK OF BLOOD CLOTS IN PEOPLE WHO:
- ARE HAVING ABDOMINAL SURGERY OR KNEE OR HIP REPLACEMENT SURGERY
- ARE BEDRIDDEN
- HAVE UNSTABLE ANGINA (CHEST PAIN), OR A HEART ATTACK.-
- THIS MEDICINE MAY ALSO BE USED LONG-TERM TO TREAT BLOOD CLOTS IN PEOPLE WITH CANCER.

Food and Drug Administration (FDA) approved .Prescription Only (POM)

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