First anticoagulant approved for preventing VTE recurrence in children

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(HealthDay)—Fragmin (dalteparin sodium) injection has been granted the first approval for subcutaneous use in preventing recurrence of symptomatic venous thromboembolism (VTE) in children aged 1 month or older, the U.S. Food and Drug Administration announced.

Fragmin has been approved for use in adults since 1994. Approval in children was based on a trial of 38 pediatric patients with symptomatic deep vein thrombosis or pulmonary embolism who were treated with Fragmin for a maximum of three months. At study completion, VTEs resolved in 21 patients, seven patients regressed, and two patients had no change. VTE did not progress in any of the patients, and one patient experienced recurrence.

Fragmin contains a boxed warning on the risk for epidural or spinal hematomas in patients who are taking low molecular weight heparins or heparinoids and are receiving neuraxial anesthesia or undergoing spinal puncture. Clinicians should consider the risk for these hematomas when scheduling patients for spinal procedures. The optimal timing between Fragmin administration and neuraxial procedures is not known.

Commonly reported side effects of Fragmin include hemorrhage, thrombocytopenia, hematoma, and transient elevation of transaminases. The FDA advises health care professionals to be cautious when treating patients with an increased risk for hemorrhage and to monitor thrombocytopenia closely. The agency also warns that benzyl alcohol preservative multiple-dose formulations should not be used in infants, and clinicians should consider the combined daily metabolic load of benzyl alcohol from multiple sources, including the Fragmin multiple-dose vial and other drugs containing benzyl alcohol. Patients should periodically undergo blood count laboratory tests and be monitored for bleeding when taking Fragmin and anticoagulants.

Approval was granted to Pfizer.

More information: More Information