Health Bulletin

NEW FDA APPROVAL FOR BLOOD CLOT THERAPY MARKS IMPORTANT DEVELOPMENT IN SUPPORTIVE CARE OF CANCER PATIENTS

(NAPSA)—According to the American Cancer Society, more than 1.3 million Americans are diagnosed with some form of cancer each year. For many patients and their loved ones, battling cancer is a long and hard-fought endeavor. But apart from the disease itself, patients must also contend with a potential danger associated with cancer and certain treatments, such as chemotherapy and surgery—an increased risk for blood clots known as venous thromboembolism, commonly called VTE.

VTE involves a blood clot that can travel from a leg vein to the lung, with potentially fatal results. Studies have shown patients with cancer have a greater risk of developing VTE than non-cancer patients.

Fortunately, the anticoagulant, or blood thinner, called FRAGMIN® (dalteparin sodium injection) was recently approved by the U.S. Food and Drug Administration for the extended treatment of blood clots in the veins to reduce the recurrence of VTE in patients with cancer. It is the first low molecular weight heparin (LMWH) to be approved for this use.

"This is an important development in supportive care for patients with cancer," said Frederick Rickles, MD, FACP, clinical professor of medicine at George Washington University Medical Center. "Physicians now have an FDA-approved low molecular weight heparin specifically for the extended treatment to reduce the recurrence of blood clots in patients with cancer."

Important Safety Information
SPINAL/EPIDURAL HEMATOMAS

When neuraxial anesthesia (epidural/spinal anesthesia) or spinal puncture is employed, patients anticoagulated or scheduled to be anticoagulated with low molecular weight heparins or heparinoids for prevention of thromboembolic complications are at risk of developing an epidural or spinal hematoma which can result in long-term or permanent paralysis.

The risk of these events is increased by the use of indwelling epidural catheters for administration of analgesia or by the concomitant use of drugs affecting hemostasis such as non steroidal anti-inflammatory drugs (NSAIDs), platelet inhibitors, or other anticoagulants. The risk also appears to be increased by traumatic or repeated epidural or spinal puncture.

Patients should be frequently monitored for signs and symptoms of neurological impairment. If neurological compromise is noted, urgent treatment is necessary.

The physician should consider the potential benefit versus risk before neuraxial intervention in patients anticoagulated or to be anticoagulated for thromboprophylaxis (also see WARNINGS, Hemorrhage and PRECAUTIONS, Drug Interactions).

FRAGMIN is contraindicated in patients with active major bleeding or with known hypersensitivity to the drug, heparin, or pork products, or with thrombocytopenia associated with a positive antiplatelet antibody test. It should be used with extreme caution in patients with a history of heparin-induced thrombocytopenia.

Patients undergoing regional anesthesia should not receive FRAGMIN for unstable angina or non–Q-wave myocardial infarction, and patients with cancer undergoing regional anesthesia should not receive FRAGMIN for extended treatment of symptomatic VTE, due to an increased risk of bleeding associated with the dosage of FRAGMIN recommended for these indications.

FRAGMIN cannot be used interchangeably (unit for unit) with unfractionated heparin or other low–molecular-weight heparins.

FRAGMIN, like other anticoagulants, should be used with extreme caution in patients who have an increased risk of hemorrhage; bleeding can occur at any site during therapy. An unexpected drop in hematocrit or blood pressure should lead to a search for a bleeding site.

In FRAGMIN clinical trials supporting non-cancer indications, platelet counts of <100,000/mm3 and <50,000/mm3 occurred in <1% and <1%, respectively.

In a clinical trial of patients with cancer and acute symptomatic VTE treated for up to 6 months in the FRAGMIN treatment arm, platelet counts of <100,000/mm3 occurred in 13.6% of patients, including 6.5% who also had platelet counts less than 50,000/mm3. In the same clinical trial, thrombocytopenia was reported as an adverse event in 10.9% of patients in the FRAGMIN arm and 8.1% of patients in the oral anticoagulant arm. FRAGMIN dose was decreased or interrupted in patients whose platelet counts fell below 100,000/mm3.

Thrombocytopenia of any degree should be monitored closely. Heparin-induced thrombocytopenia can occur with administration of FRAGMIN. The incidence of this complication is unknown at present. In clinical practice, rare cases of thrombocytopenia with thrombosis have also been observed.

The most commonly reported side effect is hematoma at the injection site.

Please see www.FRAGMIN.com or full prescribing information.

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