Fragmin® (dalteparin) – New indication

- On May 16, 2019, the FDA announced the approval of Pfizer's Fragmin (dalteparin), for the treatment of symptomatic venous thromboembolism (VTE) to reduce the recurrence of VTE in pediatric patients 1 month of age and older.
    - Fragmin is not indicated for the acute treatment of VTE.
- Fragmin is also approved for:
    - The prophylaxis of ischemic complications in unstable angina and non-Q-wave myocardial infarction, when concurrently administered with aspirin therapy
    - 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, and in medical patients who are at risk for thromboembolic complications due to severely restricted mobility during acute illness
    - The extended treatment of symptomatic VTE (proximal DVT and/or PE), to reduce the recurrence of VTE in adult patients with cancer. In these patients, the Fragmin therapy begins with the initial VTE treatment and continues for six months.
- VTE usually develops as a secondary complication of underlying clinical conditions such as a venous catheter, cancer, infection, congenital heart disease, and trauma or surgery. Pediatric VTE is associated with an increased risk of in-hospital mortality, recurrent VTE and post-thrombotic syndrome.
- Fragmin is the first anticoagulant to be FDA-approved to treat VTE in pediatric patients.
- The new indication for Fragmin was approved based on the open-label study enrolling 38 pediatric patients with or without cancer and symptomatic DVT and/or PE. Patients were treated with Fragmin for up to 3 months, with starting doses by age and weight.
    - At study completion, 21 patients (62%) achieved resolution of the qualifying VTE, 7 patients (21%) showed regression, 2 patients (6%) showed no change, and no patients showed progression of the qualifying VTE. One patient (3%) experienced a new VTE during the study while on treatment.
- Fragmin carries a boxed warning for spinal/epidural hematomas.
- The recommended starting dose of Fragmin for pediatric patients with VTE is given subcutaneously and based on patient's age and weight as follows:

Patient Age	Starting Dose
4 weeks to less than 2 years	150 IU/kg twice daily
2 years to less than 8 years	125 IU/kg twice daily
8 years to less than 17 years	100 IU/kg twice daily

    - After initiation of Fragmin, anti-Xa levels should be measured prior to the 4th dose. Doses should be adjusted in increments of 25 IU/kg to achieve target anti-Xa level between 0.5 and 1 IU/mL.

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— Whenever possible, benzyl alcohol-free formulations (prefilled syringes) should be administered to pediatric patients.