## Pradaxa® (dabigatran etexilate) – First-time generic

- Ascend launched a limited quantity of Alkem's AB-rated generic version of Boehringer Ingelheim's Pradaxa (dabigatran etexilate) 75 mg capsules and Camber launched a limited quantity of Hetero's AB-rated generic version of Pradaxa 150 mg capsules.

    - Alkem received FDA approval of an AB-rated generic version of Pradaxa 150 mg capsules on March 11, 2020. Launch date is pending.
    - Hetero received FDA approval of an AB-rated generic version of Pradaxa 75 mg capsules on May 6, 2020. Launch date is pending.
    - Active pharmaceutical ingredient (API) is in short supply for the generic products so launch quantities are delayed.

- Pradaxa is approved for the following indications:

    - To reduce the risk of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation
    - For the treatment of deep venous thrombosis (DVT) and pulmonary embolism (PE) in adult patients who have been treated with a parenteral anticoagulant for 5-10 days
    - To reduce the risk of recurrence of DVT and PE in adult patients who have been previously treated
    - For the prophylaxis of DVT and PE, in adult patients who have undergone hip replacement surgery
    - For the treatment of venous thromboembolic events (VTE) in pediatric patients 8 to less than 18 years of age who have been treated with a parenteral anticoagulant for at least 5 days
    - To reduce the risk of recurrence of VTE in pediatric patients 8 to less than 18 years of age who have been previously treated.

- Pradaxa carries a boxed warning for premature discontinuation of Pradaxa increases the risk of thrombotic events, and spinal/epidural hematoma.