

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

- Ascend launched a limited quantity of Alkem's <u>AB-rated</u> generic version of Boehringer Ingelheim's <u>Pradaxa (dabigatran etexilate)</u> 75 mg capsules and <u>Camber launched</u> a limited quantity of Hetero's <u>AB-rated</u> generic version of Pradaxa 150 mg capsules.
  - Alkem received FDA approval of an <u>AB-rated</u> generic version of Pradaxa 150 mg capsules on March 11, 2020. Launch date is pending.
  - Hetero received FDA approval of an <u>AB-rated</u> 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.



At Optum, we help create a healthier world, one insight, one connection, one person at a time. All Optum trademarks and logos are owned by Optum, Inc., in the U.S. and other jurisdictions. All other trademarks are the property of their respective owners. This document contains information that is considered proprietary to Optum Rx and should not be reproduced without the express written consent of Optum Rx. RxNews® is published by the Optum Rx Clinical Services Department.