FIRST TIME GENERIC APPROVAL

Brand Name	Pradaxa®
Generic Name	dabigatran etexilate
Drug Manufacturer	Alkem Laboratories, LLC

New Drug Approval

TYPE OF CLINICAL UPDATE

First Time Generic

FDA APPROVAL DATE

March 11, 2020

LAUNCH DATE

June 20, 2022

REVIEW DESIGNATION

Standard

TYPE OF REVIEW

Abbreviated New Drug Application (ANDA): 208040

DISPENSING RESTRICTIONS

N/A

Overview

INDICATION FOR USE

Dabigatran etexilate Capsules is a direct thrombin inhibitor indicated:

- 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 to 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.

MECHANISMS OF ACTION

Dabigatran and its acyl glucuronides are competitive, direct thrombin inhibitors. Because thrombin (serine protease) enables the conversion of fibrinogen into fibrin during the coagulation cascade, its inhibition prevents the development of a thrombus. Both free and clot-bound thrombin, and thrombin-induced platelet aggregation are inhibited by the active moieties.

DOSE FORM AND STRENGTH

Capsules: 75 mg and 150 mg

DOSE & ADMINISTRATION

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- Non-valvular Atrial Fibrillation in Adult Patients:
  - For patients with CrCl >30 mL/min: 150 mg orally, twice daily.
  - For patients with CrCl 15 to 30 mL/min: 75 mg orally, twice daily.
- Treatment of DVT and PE in Adult Patients:
  - For patients with CrCl >30 mL/min: 150 mg orally, twice daily after 5 to 10 days of parenteral anticoagulation.
  - Reduction in the Risk of Recurrence of DVT and PE in Adult Patients:
  - For patients with CrCl >30 mL/min: 150 mg orally, twice daily after previous treatment.
- Prophylaxis of DVT and PE Following Hip Replacement Surgery in Adult Patients:
  - For patients with CrCl >30 mL/min: 110 mg orally first day, then 220 mg once daily.
- Dabigatran etexilate Capsules are not substitutable on a milligram-to-milligram basis with other dabigatran etexilate dosage forms.
- Review recommendations for converting to or from other oral or parenteral anticoagulants.
- Temporarily discontinue dabigatran etexilate Capsules before invasive or surgical procedures, when possible, then restart promptly.