**INDICATION-SPECIFIC DOSAGE STRENGTHS AVAILABLE:**
75 mg, 110 mg, AND 150 mg

**Recommended Dosing**

<table>
<thead>
<tr>
<th>INDICATION</th>
<th>DOSAGE</th>
<th>CRITERIA</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Reduce Stroke Risk in NVAF</strong></td>
<td>150 mg Twice Daily</td>
<td>Patients with CrCl &gt;30 mL/min</td>
</tr>
<tr>
<td></td>
<td>75 mg Twice Daily</td>
<td>Patients with CrCl 15-30 mL/min</td>
</tr>
<tr>
<td><strong>Treat DVT &amp; PE or Reduce Risk of Recurrence</strong></td>
<td>150 mg Twice Daily For treatment only: Initial treatment with parenteral anticoagulant for 5-10 days</td>
<td>Patients with CrCl &gt;30 mL/min</td>
</tr>
<tr>
<td></td>
<td>110 mg 1-4 hours post-surgery and after achieving hemostasis, then 220 mg Once Daily for 28-35 days</td>
<td>Patients with CrCl 15-30 mL/min</td>
</tr>
</tbody>
</table>

**Avoid co-administration in patients with:**
- NVAF: CrCl <30 mL/min
- DVT/PE & HIP: CrCl <50 mL/min

**INDICATIONS AND USAGE**

Pradaxa® (dabigatran etexilate mesylate) capsules is indicated:
- to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation;
- for the prophylaxis of deep vein thrombosis and pulmonary embolism in patients who have undergone hip replacement surgery

**IMPORTANT SAFETY INFORMATION ABOUT PRADAXA**

**WARNING:** (A) Premature Discontinuation of Pradaxa Increases the Risk of Thrombotic Events
Premature discontinuation of any oral anticoagulant, including Pradaxa, increases the risk of thrombotic events. If anticoagulation with Pradaxa is discontinued for a reason other than pathological bleeding or completion of a course of therapy, consider coverage with another anticoagulant

Please see additional Important Safety Information about Pradaxa on next page and full Prescribing Information, including boxed WARNING and Medication Guide.
**WARNING:** (A) PREMATURE DISCONTINUATION OF PRADAXA INCREASES THE RISK OF THROMBOTIC EVENTS, (B) SPINAL/EPIDURAL HEMATOMA

**SPINAL/EPIDURAL HEMATOMA**

Epidural or spinal hematomas may occur in patients treated with PRADAXA who are receiving neuraxial anesthesia or undergoing spinal puncture. These hematomas may result in long-term or permanent paralysis.

Epidural or spinal hematomas may occur in patients treated with PRADAXA who are receiving neuraxial anesthesia or undergoing spinal puncture. These hematomas may result in long-term or permanent paralysis.

- use of indwelling epidural catheters
- concomitant use of other drugs that affect hemostasis, such as non-steroidal anti-inflammatory drugs (NSAIDs), platelet inhibitors, other anticoagulants
- a history of traumatic or repeated epidural or spinal punctures
- a history of spinal deformity or spinal surgery
- optimal timing between the administration of PRADAXA and neuraxial procedures is not known

Monitor patients frequently for signs and symptoms of neurological impairment. If neurological compromise is noted, urgent treatment is necessary. Consider the benefits and risks before neuraxial intervention in patients who are or will be anticoagulated.

**CONTRAINDICATIONS**

PRADAXA is contraindicated in patients with:
- active pathological bleeding;
- known serious hypersensitivity reaction to PRADAXA (e.g., anaphylactic reaction or anaphylactic shock);
- mechanical prosthetic heart valve

**WARNINGS & PRECAUTIONS**

**Increased Risk of Thrombotic Events after Premature Discontinuation**

Premature discontinuation of any oral anticoagulant, including PRADAXA, in the absence of adequate alternative anticoagulation increases the risk of thrombotic events. If PRADAXA is discontinued for a reason other than pathological bleeding or completion of a course of therapy, consider coverage with another anticoagulant and restart PRADAXA as soon as medically appropriate.

**Risk of Bleeding**

- PRADAXA increases the risk of bleeding and can cause significant and, sometimes, fatal bleeding. Promptly evaluate any signs or symptoms of blood loss (e.g., a drop in hemoglobin and/or hematocrit or hypotension). Discontinue PRADAXA in patients with active pathological bleeding.
- Risk factors for bleeding include concomitant use of medications that increase the risk of bleeding (e.g., anti-platelet agents, heparin, fibrinolytic therapy, and chronic use of NSAIDs). PRADAXA’s anticoagulant activity and half-life are increased in patients with renal impairment.
- Reversal of Anticoagulant Effect: A specific reversal agent (idarucizumab) for dabigatran is available when reversal of the anticoagulant effect of dabigatran is needed:
  - For emergency surgery/urgent procedures
  - In life-threatening or uncontrolled bleeding
- Hemodialysis can remove dabigatran; however clinical experience for hemodialysis as a treatment for bleeding is limited. Prothrombin complex concentrates or recombinant Factor VIIa may be considered but their use has not been evaluated. Prothrombin complex concentrates where thrombocytopenia is present or long-acting antiplatelet drugs have been used.

**Increased Risk of Thrombosis in Patients with Triple-Positive Antiphospholipid Syndrome**

There is an increased risk of thrombosis in patients with triple-positive antiphospholipid syndrome. PRADAXA use is not recommended.

**ADVERSE REACTIONS**

The most common adverse reactions reported with PRADAXA were related to gastritis-like symptoms and bleeding.

**Other Measures Evaluated**

In NVAF patients, a higher rate of clinical MI was reported in patients who received PRADAXA (0.7/100 patient-years for 150 mg dose) than in those who received warfarin (0.6).

**USE IN SPECIFIC POPULATIONS**

**Pregnancy:** The limited available data on PRADAXA use in pregnant women are insufficient to determine drug-associated risks for adverse developmental outcomes.

**Lactation:** Breastfeeding is not recommended.

**Geriatric:** Risk of bleeding increases with age.

Please see additional Important Safety Information about PRADAXA on previous page and full Prescribing Information, including boxed WARNING and Medication Guide.