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 treatment of deep venous thrombosis and pulmonary embolism in patients who have been treated with a parenteral anticoagulant for 5-10 days;
- to reduce the risk of recurrence of deep venous thrombosis and pulmonary embolism in patients who have been previously treated;
- 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, (B) SPINAL/EPIDURAL HEMATOMA
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.

(B) 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. Consider these risks when scheduling patients for spinal procedures. Factors that can increase the risk of developing epidural or spinal hematomas in these patients include:
- 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.
ADVERSE REACTIONS
The most serious adverse reactions reported with PRADAXA were related to bleeding.

NVAF
- Most frequent adverse reactions leading to discontinuation of PRADAXA were bleeding & gastrointestinal (GI) events
- PRADAXA 150 mg resulted in higher rates of major and any GI bleeds compared to warfarin
- In patients ≥75 years of age, the risk of major bleeding may be greater with PRADAXA vs warfarin
- Patients on PRADAXA 150 mg had an increased incidence of GI adverse reactions. These were dyspepsia (including abdominal pain upper, abdominal pain, abdominal discomfort, and epigastric discomfort) and gastritis-like symptoms (including GERD, esophagitis, erosive gastritis, gastric hemorrhage, hemorrhagic erosive gastritis, hemorrhagic erosive gastritis, and GI ulcer)

DVT/PE
- Rates of any GI bleeds were higher in patients receiving PRADAXA 150 mg vs warfarin and placebo
- In the active-controlled studies, there was a higher rate of clinical myocardial infarction (MI) in PRADAXA patients [20 (0.66/100 patient-years)] vs warfarin [5 (0.17/100 patient-years)]. In the placebo-controlled study, there was similar rate of non-fatal and fatal clinical MI in PRADAXA patients [1 (0.32/100 patient-years)] vs placebo [1 (0.34/100 patient-years)]
- GI adverse reactions were similar in patients receiving PRADAXA 150 mg vs warfarin. They were dyspepsia (including abdominal pain upper, abdominal pain, abdominal discomfort, and epigastric discomfort) and gastritis-like symptoms (including gastritis, GERD, esophagitis, erosive gastritis and gastric hemorrhage)

DVT/PE After Hip Replacement Surgery
- Rate of major GI bleeds in patients receiving PRADAXA 220 mg and enoxaparin was the same; rate of any GI bleeds was higher in patients receiving PRADAXA 220 mg vs enoxaparin
- GI adverse reactions were the same in patients receiving PRADAXA 220 mg vs enoxaparin. These were dyspepsia (including abdominal pain upper, abdominal pain, abdominal discomfort, and epigastric discomfort) and gastritis-like symptoms (including gastritis, GERD, esophagitis, erosive gastritis and gastric hemorrhage)
- Clinical MI was reported in 2 (0.1%) patients who received PRADAXA 220 mg and 6 (0.3%) patients who received enoxaparin

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.