Is Dabigatran (Pradaxa®) an Option for Your Patient?
(Note: A generic product is on the market. Availability on provincial formularies varies by province)

**Indications**
- Non-Valvular Atrial Fibrillation (NVAF)* to prevent stroke & systemic embolism
- Acute VTE treatment & prevention of recurrent VTE [for deep vein thrombosis (DVT) and pulmonary embolism (PE)]
- Prevention of venous thromboembolic events (VTE) in elective total hip or knee replacement surgery (THR, TKR)

*CCS definition: AF without mechanical heart valves, rheumatic mitral stenosis, or moderate/severe non-rheumatic mitral stenosis.

**Requirements** - NOTE: Dabigatran accumulates in renal dysfunction.
- Stable creatinine clearance (CrCl) 30 mL/min or more

**Contraindications**
- Mechanical heart valves
- Dabigatran, like other anticoagulants, is contraindicated in patients at high risk for bleeding
- Pregnant/Breastfeeding: Safety & dosing has not been studied. Use is NOT recommended
- Drug Interactions: Significant drug interactions involving P-glycoprotein - See below.

**Potential Limitations**
- Not recommended in hemodynamically unstable acute PE or those requiring thrombectomy or thrombolysis
- Not recommended in antiphospholipid syndrome with a history of thrombosis (especially triple positive)
- Drug Interactions: AVOID rifampin, select azole antifungals & anticonvulsants, HIV protease inhibitors, glecaprevir/pibrentasvir, ticagrelor, St. John’s Wort, and other strong P-gp inducers and inhibitors as there is minimal knowledge of clinical outcomes
- Rapid decline in anticoagulant effect after a missed dose; adherence is critical
- Limited data with extremes of weight (under 50 kg; over 120 kg or BMI > 40)
- Less than 18 years of age: Safety and dosing has not been established
- Acute treatment of VTE: Must be preceded by 5-10 days of parenteral anticoagulant
- Dyspepsia
- AF: dabigatran 150mg BID showed higher GI bleed rate than warfarin, but no difference in overall bleeding events

**May offer an advantage over warfarin if:**
- Difficulty stabilizing on warfarin for reasons other than poor medication adherence
- INR monitoring is problematic (e.g. poor venous access, frequent travel, remote location). NOTE: Use of warfarin with point-of-care (POC) INR testing (e.g. Coaguchek XS™) may be an alternative solution
- AF: superior reduction in rate of stroke and systemic embolism with dabigatran 150 mg bid, lower rate major bleeding with 110 mg bid, lower intracranial hemorrhage with both doses vs. warfarin
- Availability of idarucizumab for emergency surgery/urgent procedures or life-threatening/ uncontrolled bleeding

**Dosing Recommendations**

<table>
<thead>
<tr>
<th>Indication</th>
<th>CrCl 50 mL/min or greater</th>
<th>CrCl 30–49 mL/min</th>
<th>CrCl less than 30 mL/min</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stroke Prevention in Non-Valvular Atrial Fibrillation</td>
<td>• 150 mg BID</td>
<td>• 110 mg BID if ≥ 80 years of age. Also consider if &gt;75 years old and ONE or more risk factor for bleeding (e.g. CrCl 30 - 49 mL/min, on antiplatelets, or interacting medication, etc.)</td>
<td>Contraindicated</td>
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<tr>
<td>Acute DVT/PE Treatment</td>
<td>Parenteral Anticoagulant x 5-10 days, then dabigatran as per AF dosing</td>
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<tr>
<td>Hip &amp; Knee Replacement</td>
<td>110 mg initial dose*, then 220 mg once daily x 10 (TKR) to 28-35 days (THR)</td>
<td>75 mg initial dose*, then 150 mg once daily x 10 (TKR) to 28-35 days (THR)</td>
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</tbody>
</table>

*110 mg BID dose not studied for VTE treatment, but is suggested as per AF indication above
*Initiate 1-4 h after surgery once hemostasis secured. If not started day of surgery, initiate with 220 mg once daily

**Inform Your Patient:**
- Carry information indicating they are on an anticoagulant and inform their healthcare providers, including dentists
- Product monograph indicates must remain in original blister package or manufacturer’s bottle. Recent data indicates stability outside of the manufacturer’s blister packs, but the clinical implications of this storage are not yet known
- Swallow capsule whole - no chewing, crushing, or opening capsule as this may dramatically ↑ blood drug levels
- Must be taken TWICE daily with or without food; adherence is essential to avoid treatment failure
- Report symptoms/signs of dyspepsia, bleeding, stroke, DVT/PE

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Page 1 of 2 Collaborative Learning on Thrombosis (CLOT) – Canadian Prairie pharmacists with an interest in thromboembolic disorders
This is intended only as a general reference to supplement existing knowledge of healthcare professionals in Canada & is not a substitute for sound clinical judgement. CLOT members cannot be held responsible for any harm as a result of application of this information (July 2020)
Anticoagulation around Invasive Procedures

Management of Bleeding Episodes with Dabigatran

Switching Between Agents

Reference:

9. Pradaxa® Full Prescribing Information (Boehringer Ingelheim Pharmaceuticals, Inc. USA),July 2020.  