

## Dabigatran (Pradaxa®) Considerations for Use\*

US/FDA Approved Indications: Stroke Prevention in Non-valvular Atrial Fibrillation

<b>Mechanism of Action</b>	Direct thrombin inhibitor
<b>Dosing<sup>†</sup></b>	<p><u>Adult:</u> 150 mg PO twice daily</p> <p><u>Elderly:</u> No dosage adjustment necessary</p> <p><u>Hepatic Impairment:</u> No dosage adjustment necessary</p> <p><u>Renal Impairment:</u>  <u>CrCl 15 to 30 mL/min:</u> 75 mg PO twice daily  <u>CrCl &lt; 15 mL/min or on dialysis:</u> not recommended</p>
<b>Contraindications</b>	Active pathological bleeding, mechanical prosthetic heart valve
<b>Major Side Effects</b>	Hemorrhagic event
<b>Dosage forms and Strengths</b>	<u>PO:</u> 75, 150mg capsules
<b>Reversal</b>	<p>There is no rapid reversal agent for dabigatran.</p> <ul style="list-style-type: none"> <li>Discontinue dabigatran</li> <li>Limited data shows that hemodialysis can remove 49-57% of dabigatran over 4 hours</li> <li>Measurement of aPTT or ECT may help guide therapy</li> </ul> <p><u>Surgery and interventions:</u></p> <ul style="list-style-type: none"> <li>If possible, discontinue for 1 to 2 days with CrCl ≥ 50 mL/min or 3 to 5 days with CrCl &lt; 50mL/min prior to procedure.</li> <li>Longer times may be required for patients undergoing major surgery, spinal puncture, or placement of epidural or spinal catheter/port, in who complete homeostasis may be required</li> </ul>
<b>Conversion to/from other drugs</b>	<p><u>From dabigatran to warfarin:</u></p> <ul style="list-style-type: none"> <li>If CrCl ≥ 50 mL/min, start warfarin 3 days before discontinuing dabigatran</li> <li>If CrCl 30 to 50 mL/min, start warfarin 2 days before discontinuing dabigatran</li> <li>If CrCl 15 to 30 mL/min, start warfarin 1 day before discontinuing dabigatran</li> <li>If CrCl &lt; 15 mL/min, no recommendations can be made</li> </ul> <p><u>From dabigatran to parenteral anticoagulant:</u></p> <ul style="list-style-type: none"> <li>Wait 12 hrs (CrCl ≥ 30mL/min) or 24 hrs (CrCl &lt; 30mL/min) after last dabigatran dose before initiating parenteral anticoagulant</li> </ul> <p><u>From warfarin to dabigatran:</u></p> <ul style="list-style-type: none"> <li>Discontinue warfarin and start dabigatran when INR &lt; 2</li> </ul> <p><u>From parenteral anticoagulant to dabigatran:</u></p> <ul style="list-style-type: none"> <li>Start dabigatran 0 to 2 hrs before the time that the next dose of parenteral anticoagulant was to have been given or initiate when discontinuing IV continuous heparin</li> </ul>

<b>Special Notes</b>	<p>Has many potential drug interactions.</p> <ul style="list-style-type: none"> <li>• Do not use with P-gp inducers (ex. rifampin).</li> <li>• Do not use with P-gp inhibitors and CrCl &lt; 30 mL/min.</li> <li>• With concomitant dronedarone or systemic ketoconazole in patients with CrCl 30 to 50 mL/min, consider using a lower dose of dabigatran (75 mg PO twice daily).</li> </ul> <p>Can increase INR. INR will better reflect only warfarin's effect when the patient has been off the dabigatran for at least 2 days.</p>
<b>Counseling</b>	<p>DO NOT break, chew or open the capsules.</p> <p>Keep this medication in its original bottle or blister package to protect it from moisture. Do <u>not</u> put this medication into a pillbox or pill organizer.</p> <p>Tightly close the bottle right away after you take the dose.</p> <p>Only remove the medication from the blister package when it is time to take the dose.</p> <p>When you open a new bottle, write down the date that you opened the bottle. Discard the bottle 4 months after it was first opened, even if you have not taken all the medication in the bottle.</p> <p>Do not discontinue this medication without talking to the healthcare provider who prescribed it.</p> <p>Consult healthcare professional prior to using new drug (prescription, OTC, herbal).</p> <p>Report signs and symptoms of bleeding (e.g., unexpected bleeding or bleeding that lasts a long time; red or black, tarry stool; pink or brown urine; unusual bruising; coughing up blood; vomiting blood or vomit that looks like coffee grounds; unexplained pain, swelling, or joint pain; unusual headaches, dizziness, or weakness; recurring nose bleeds).</p> <p>Tell your healthcare professional if you have had or will have surgery to place a prosthetic heart valve.</p> <p>Tell your healthcare professional if you are pregnant or plan to become pregnant or are breastfeeding or plan to breastfeed during treatment.</p>

\*Refer to prescribing information for more complete information.

†Dosages given in the table may differ from those recommended by the manufacturers.

Sources:

1. American College of Cardiology (ACC), American Heart Association (AHA), and Heart Rhythm Society (HRS). *2011 ACCF/AHA/HRS Focused Update on the Management of Patients With Atrial Fibrillation (Update on Dabigatran)*. Washington, DC: American College of Cardiology Foundation. 2011.
2. Pradaxa® Prescribing information, 12/19/12.
3. Chest Supplement, Antithrombotic Therapy and Prevention of Thrombosis, 9<sup>th</sup> edition, American College of Chest Physicians.