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P.E.I. Pharmacare

Pharmacists' Bulletin

Issue (2013-2) **(February 5, 2013)**

NEW PRODUCT(S) ADDED TO THE PEI PHARMACARE FORMULARY
(Effective Date:February 18, 2013)

Product (Generic Name)	Product (Brand Name)	Strength	Dosage Form	DIN	MFR
Dabigatran	**Pradaxa**	110 mg 150 mg	Capsule Capsule	02312441 02358808	BOE BOE
Criteria	For the prevention of stroke and systemic embolism in at-risk patients with non-valvular atrial fibrillation for whom: a) Anticoagulation is inadequate following at least a two month trial of warfarin; or b) Warfarin is contraindicated or not possible due to inability to regularly monitor through International Normalized Ratio (INR) testing (i.e. no access to INR testing services at a laboratory, clinic, pharmacy, and at home). The following patient groups are excluded from coverage for dabigatran for atrial fibrillation: a) Patients with impaired renal function (creatinine clearance or estimated glomerular filtration rate < 30 mL/min) b) Patients 75 years of age or older without documented stable renal function c) Patients with hemodynamically significant rheumatic valvular heart disease, especially mitral stenosis d) Patients with prosthetic heart valves Notes: 1. At-risk patients with atrial fibrillation are defined as those with a $CHADS_2$ score of $\geq$ 1. 2. Inadequate anticoagulation is defined as INR testing results that are outside the desired INR range for at least 35% of the tests during the monitoring period (i.e. adequate anticoagulation is defined as INR test results that are within the desired INR range for at least 65% of the tests during the monitoring period). 3. Since renal impairment can increase bleeding risk, renal function should be regularly monitored. Other factors that increase bleeding risk should also be assessed and monitored (see dabigatran product monograph). 4. Documented stable renal function is defined as creatinine clearance or estimated glomerular filtration rate that maintained for at least three months (i.e. 30-49 mL/min for 110 mg twice daily dosing or $\geq$ 50 mL/min for 150 mg twice daily dosing). 5. There is currently no data to support that dabigatran provides adequate anticoagulation in patients with rheumatic valvular disease or those with prosthetic heart valves, so dabigatran is not recommended in these populations. 6. Patients starting dabigatran should have ready access to appropriate medical services to manage a major bleeding event.				
Program Eligibility	Family Health Benefit / Financial Assistance / Nursing Home / Seniors				

Rivaroxaban	**Xarelto**	15 mg	Tablet	02378604	BAY
		20 mg	Tablet	02378612	BAY

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Program Eligibility	Family Health Benefit / Financial Assistance / Nursing Home / Seniors