

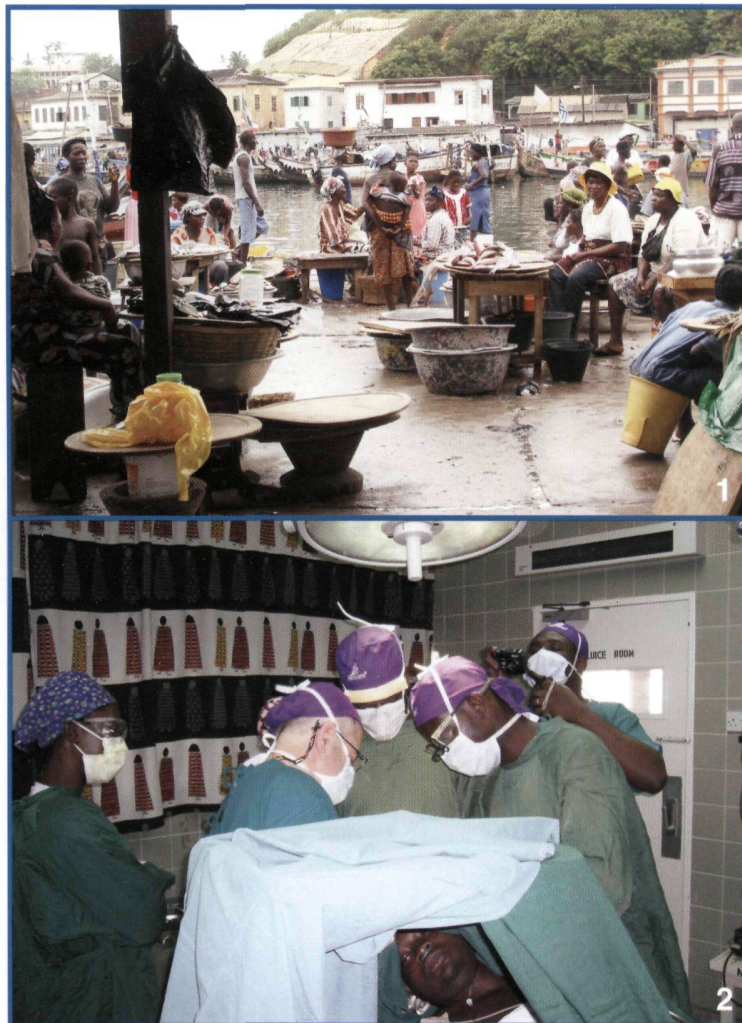


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Canadian Journal of Neurological Sciences

Volume 38 Number 2 March 2011



Out of Africa, for now - pages 373-374
From the Reflections article by Mark Bernstein

Figure 1: Fishmarket in Cape Coast, Ghana. **Figure 2:** Teaching awake brain tumour surgery to local surgeons at Korle Bu Teaching Hospital, Accra, Ghana.

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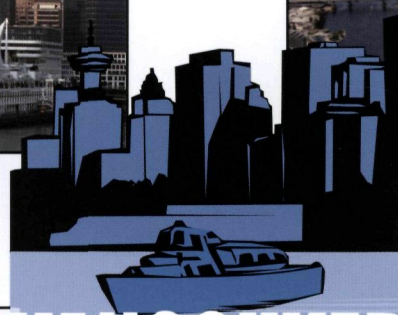
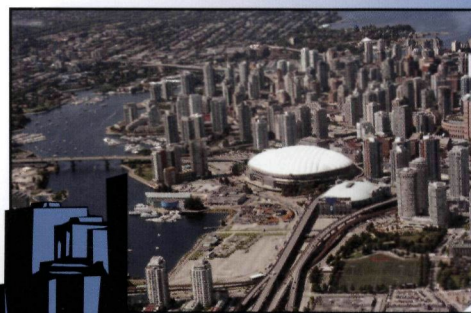
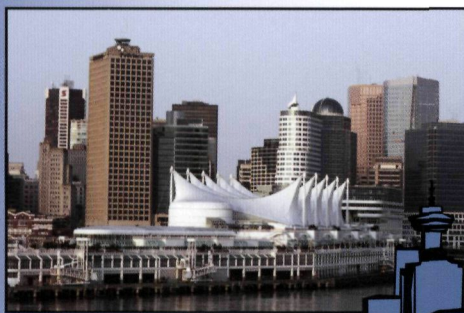


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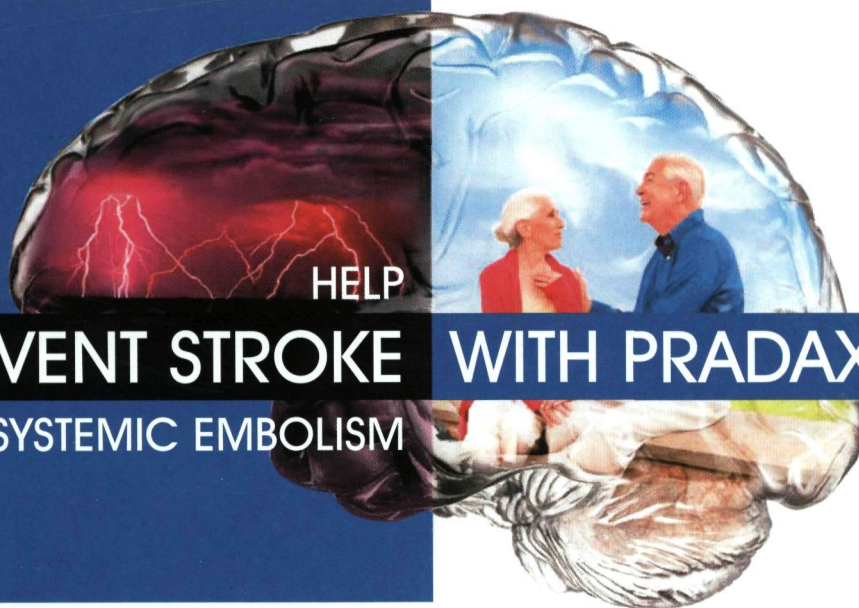
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NEW Pr PRADAX™ 150 mg BID

NOW INDICATED FOR THE PREVENTION OF STROKE AND SYSTEMIC EMBOLISM IN PATIENTS WITH ATRIAL FIBRILLATION, IN WHOM ANTICOAGULATION IS APPROPRIATE.¹



PREVENT STROKE AND SYSTEMIC EMBOLISM WITH PRADAX

For patients with atrial fibrillation, PRADAX demonstrated:

35% reduced risk of stroke or systemic embolism vs. warfarin^{1-3*†}

Dabigatran 150 mg BID (1.1%/yr) vs. warfarin (1.7%/yr), $p=0.0001$.

59% reduced risk of intracranial bleeding[‡] vs. warfarin^{1-3*§}

Dabigatran 150 mg BID (0.3%/yr) vs. warfarin (0.8%/yr), $p<0.0001$.

No INR monitoring or dose titration¹

PRADAX (dabigatran etexilate) is indicated for the prevention of stroke and systemic embolism in patients with atrial fibrillation, in whom anticoagulation is appropriate.

PRADAX is contraindicated in patients with: severe renal impairment (CrCL <30 mL/min); hemorrhagic manifestations, bleeding diathesis, or patients with spontaneous or pharmacological impairment of hemostasis; lesions at risk of clinically significant bleeding, e.g. extensive cerebral infarction (hemorrhagic or ischemic) within the last 6 months, active peptic ulcer disease with recent bleeding; concomitant treatment with the strong P-glycoprotein (P-gp) inhibitors, i.e. oral ketoconazole, and with known hypersensitivity to dabigatran, dabigatran etexilate or to any ingredient in the formulation or component of the container.

Bleeding is the most relevant side effect of PRADAX; bleeding of any type or severity occurred in long-term treatment in 16.5% of patients with atrial fibrillation treated for the prevention of stroke and systemic embolism. As with all anticoagulants, PRADAX should be used with caution in circumstances associated with an increased risk of bleeding. Bleeding can occur at any site during therapy with PRADAX. An unexplained fall in hemoglobin and/or hematocrit or blood pressure should lead to a search for a bleeding site. Patients at high risk of bleeding should not be prescribed PRADAX. Close clinical surveillance (looking for signs of bleeding or anemia) is recommended throughout the treatment period, especially if risk factors are combined. **Should severe bleeding occur, treatment with PRADAX must be discontinued and the source of bleeding investigated promptly.** Patients who develop acute renal failure must discontinue PRADAX. In patients who are bleeding, an aPTT test may be useful to assist in determining an excess of anticoagulant activity, despite its limited sensitivity. An aPTT >80 sec at trough, i.e. when the next dose is due, is associated with a higher risk of bleeding.

Agents that may enhance the risk of hemorrhage should not be administered concomitantly with PRADAX, or, if necessary, should only be administered with caution. **Treatments that should NOT be administered concomitantly with PRADAX due to increase in bleeding risk include: unfractionated heparin and heparin derivatives, low molecular weight heparins (LMWH), fondaparinux, bivalirudin, thrombolytic agents, GPIIb/IIIa receptor antagonists, ticlopidine, sulfapyrazone and vitamin K antagonists such as warfarin. The concomitant use of PRADAX with the following treatments has not been studied and may increase the risk of bleeding: rivaroxaban, prasugrel and the strong P-gp inhibitors itraconazole, tacrolimus, cyclosporine, ritonavir, tipranavir, nelfinavir and saquinavir.** Unfractionated heparin may be administered at doses necessary to maintain a patent central venous or arterial catheter. In patients with atrial fibrillation treated for the prevention of stroke and systemic embolism, the co-administration of oral anti-platelet (including ASA and clopidogrel) and NSAID therapies increases the risk of bleeding by about two-fold (see ACTION and CLINICAL PHARMACOLOGY,

Special Populations, Pharmacokinetic Interactions). If necessary, co-administration of low-dose ASA, i.e. ≤ 100 mg daily with PRADAX may be considered for other indications than stroke prevention in atrial fibrillation. The concomitant use of PRADAX with the strong P-gp inducer, rifampicin, reduces dabigatran plasma concentrations. Other P-gp inducers such as St. John's Wort or carbamazepine are also expected to reduce dabigatran plasma concentrations and should be co-administered with caution.

The most common adverse events observed in $\geq 1\%$ of PRADAX 150 mg BID patients and 110 mg BID patients was anemia (1.6%, 1.2%), epistaxis (1.1%, 1.1%), gastrointestinal hemorrhage (4.6%, 3.3%), urogenital hemorrhage (1.4%, 1.1%), abdominal pain (2.2%, 2.3%), diarrhea (1.2%, 1.3%), dyspepsia (3.9%, 4.2%) and nausea (1.2%, 1.0%), respectively. Gastrointestinal adverse reactions occurred more often with dabigatran etexilate than warfarin. These were related to dyspepsia (including upper abdominal pain, abdominal pain, abdominal discomfort, epigastric discomfort) or gastritis-like symptoms (including GERD, esophagitis, erosive gastritis, gastric hemorrhage, hemorrhagic gastritis, hemorrhagic erosive gastritis and gastrointestinal ulcer). Gastrointestinal hemorrhage occurred at a higher frequency with PRADAX 150 mg BID and 110 mg BID (4.6%, 3.3%, respectively) compared to warfarin (2.6%). The underlying mechanism of the increased rate of GI bleeding has not been established.

Allergic reactions or drug hypersensitivity including urticaria, bronchospasm, rash and pruritus have been reported in patients who received dabigatran etexilate. Rare cases of anaphylactic reactions have also been reported.

Patients at an increased risk of bleeding should be closely monitored clinically. A coagulation test, such as aPTT may help to identify patients with an increased bleeding risk caused by excessive dabigatran exposure.

For complete prescribing information, please refer to the Product Monograph.

*A randomized non-inferiority trial of 18,113 AF patients at risk of stroke. Patients received dabigatran 110 mg BID or 150 mg BID (blinded arm) and adjusted doses of warfarin (unblinded arm).

†Stroke or systemic embolism: dabigatran 150 mg BID ($n=6076$, no. of events=134) vs. warfarin ($n=6022$, no. of events=202).

‡Intracranial bleeding includes adjudicated hemorrhagic stroke, subarachnoid, and/or subdural bleeding.

§Intracranial bleeding: dabigatran 150 mg BID (no. of events=38) vs. warfarin (no. of events=90).

References: 1. Pradax Product Monograph. Boehringer Ingelheim (Canada) Ltd., 11/08/10. 2. Connolly SJ *et al.* Dabigatran versus Warfarin in Patients with Atrial Fibrillation. *N Engl J Med.* 2009;361:1139-1151. 3. Connolly SJ *et al.* Newly Identified Events in the RE-LY Trial. *N Engl J Med.* 2010;363:1875-1876 supp appendix.

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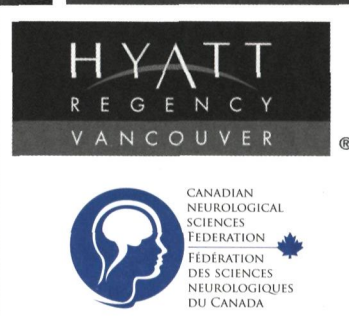




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* Fictitious patient. May not be representative of all fibromyalgia cases.



FACED WITH PAIN*

IN HER STRUGGLE WITH FIBROMYALGIA

First treatment indicated in Canada for adults for the management of pain associated with

fibromyalgia¹

Pregabalin: first-line treatment for chronic **neuropathic pain²**

DEMONSTRATED SIGNIFICANT RELIEF IN PAIN AND PAIN-RELATED SLEEP DIFFICULTIES IN FIBROMYALGIA¹

Demonstrated powerful, rapid and sustained pain relief^{1,3-5}

In fibromyalgia:

- In a 14 week study, LYRICA demonstrated significant pain reduction as early as week 1 ($p < 0.05$ for all doses). Mean changes in pain scores at the end of the study for LYRICA-treated patients were significantly greater versus placebo (300 mg/day, $n=183$: -1.75, $p=0.0009$; 450 mg/day, $n=190$: -2.03, $p < 0.0001$; 600 mg/day, $n=188$: -2.05, $p < 0.0001$; placebo, $n=184$: -1.04)³
- In another study of 26 weeks' duration of patients who initially responded to LYRICA during a 6-week, open-label phase, 68% of those who continued on their optimized dose ($n=279$) maintained a treatment response versus 39% of those on placebo ($n=287$). The time to loss of therapeutic response was longer in the LYRICA group ($p < 0.0001$)⁴

Also in neuropathic pain (NeP):

- Sustained pain relief (starting at week 2 for LYRICA 150-600 mg/day, $n=141$; $p < 0.05$ vs placebo, $n=65$) was demonstrated throughout a 12 week study in patients with DPN or PHN⁵

Demonstrated effective in relieving pain-related sleep difficulties^{1,6}

In fibromyalgia:

- In a 13 week study, LYRICA reduced overall MOS-Sleep Scale scores significantly more at the end of the study vs. placebo (300 mg/day -19.1, $p=0.0174$; 450 mg/day: -20.41, $p=0.0026$; 600 mg/day: -19.49, $p=0.0101$; placebo: -14.29)⁶

Also in NeP:

- LYRICA reduced sleep disturbances across several studies in DPN and PHN, of 8-12 weeks duration¹

Flexible dosing across all indications^{1†}

LYRICA (pregabalin) is indicated for the management of neuropathic pain associated with diabetic peripheral neuropathy (DPN), postherpetic neuralgia (PHN) and spinal cord injury in adults. LYRICA may be useful in the management of central neuropathic pain in adults. LYRICA is indicated for the management of pain associated with fibromyalgia in adults. The efficacy of LYRICA in the management of pain associated with fibromyalgia for up to 6 months was demonstrated in a placebo-controlled trial in patients who had initially responded to LYRICA during a 6-week open-label phase.

LYRICA is contraindicated in patients who are hypersensitive to pregabalin or to any ingredient in the formulation or component of the container.

The most commonly observed adverse events ($\geq 5\%$ and twice the rate as that seen with placebo) in the recommended dose range of 150 mg/day to 600 mg/day in PHN and DPN patients were: dizziness (9.0-37.0%), somnolence (6.1-24.7%), peripheral edema (6.1-16.2%), and dry mouth (1.9-14.9%) and were dose related; in spinal cord injury patients: somnolence (41.4%), dizziness (24.3%), asthenia (15.7%), dry mouth (15.7%), edema (12.9%), constipation (12.9%), amnesia (10.0%), myasthenia (8.6%), amblyopia (8.6%), and thinking abnormal (8.6%); in fibromyalgia patients: dizziness (37.5%), somnolence (18.6%), weight gain (10.6%), dry mouth (7.9%), blurred vision (6.7%), and peripheral edema (6.1%). In LYRICA-treated fibromyalgia patients, the most commonly observed dose-related adverse events were: dizziness (22.7-46.5%), somnolence (12.9-20.7%), weight gain (7.6-13.7%), peripheral edema (5.3-10.8%). The most commonly observed adverse events in the PHN, DPN, spinal cord injury and fibromyalgia patients were usually mild to moderate in intensity. Discontinuation rates due to adverse events for LYRICA and placebo, respectively, were 9% and 4% in DPN, 14% and 7% in PHN, 21% and 13% in spinal cord injury, and 20% and 11% in fibromyalgia. There was a dose-dependent increase in rate of discontinuation due to adverse events in fibromyalgia.

There have been post-marketing reports of angioedema in patients, some without reported previous history/episodes, including life-threatening angioedema with respiratory compromise. Caution should be exercised in patients with previous history/episodes of angioedema and in patients who are taking other drugs associated with angioedema.

In clinical trials and in post-marketing experience, there have been reports of patients, with or without previous history, experiencing renal failure alone or in combination with other medications. Caution is advised when prescribing to the elderly or those with any degree of renal impairment.

There have been post-marketing reports of events related to reduced lower gastrointestinal tract function (e.g., intestinal obstruction, paralytic ileus, and constipation) in patients, some without reported previous history/episode(s), during initial/acute and chronic treatment with LYRICA, primarily in combination with other medications that have the potential to produce constipation. Some of these events were considered serious and required hospitalization. In a number of instances, patients were taking opioid analgesics including tramadol. Caution should be exercised when LYRICA and opioid analgesics are used in combination, and measures to prevent constipation may be considered, especially in female patients and elderly as they may be at increased risk of experiencing lower gastrointestinal-related events.

Dosage reduction is required in patients with renal impairment (creatinine clearance <60 mL/min) and in some elderly patients as LYRICA is primarily eliminated by renal excretion.

Please see Prescribing Information for complete Warnings and Precautions, Adverse Reactions, Dosage and Administration and patient selection criteria.

† Please consult Prescribing Information for complete Dosage and Administration instructions.



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