PUBLIC COMMUNICATION
Health Canada Endorsed Important Safety Information on Pradax® (dabigatran etexilate)

March 21, 2012

Subject: Update to Pradax® (dabigatran etexilate) labelling regarding assessment of kidney function and use in patients with certain types of heart valve disease or artificial heart valves

Boehringer Ingelheim (Canada) Ltd., in consultation with Health Canada, would like to inform you of new recommendations for Pradax® (dabigatran etexilate).

Pradax® is a blood thinner prescribed to patients who have a heart condition called atrial fibrillation (irregular heartbeat) to prevent strokes, as well as to patients following hip or knee replacement surgery to prevent blood clots.[1] The labelling of Pradax® has been strengthened to include new recommendations to healthcare professionals on selecting and managing patients treated with Pradax®.

A summary of these recommendations are listed below:

- Because reduced kidney function is a risk factor for bleeding while taking Pradax®:
  - Your doctor may test your kidney function before starting therapy with Pradax® and at least annually thereafter. Pradax® should not be used if you have severely reduced kidney function or your kidneys do not function.
  - If you are older than 75 years of age or if you have moderately reduced kidney function your doctor may test your kidney function during treatment with Pradax® at least once a year.
- Pradax® is not recommended if you have an artificial heart valve or severe heart valve disease associated with clinical symptoms like shortness of breath.

A risk of bleeding is present with blood thinning medicines, including Pradax®. Bleeding episodes can be life-threatening or even fatal.

Before you use Pradax® make sure you inform your health care professional if you have kidney function problems. If during treatment with Pradax® you stop producing urine you should inform your doctor immediately.

You should not stop taking Pradax® without talking to your healthcare professional. Stopping use of your blood thinning medicine suddenly can put you at risk of a stroke.

Discuss any questions or concerns about Pradax® with your healthcare professional.

Boehringer Ingelheim (Canada) Ltd. has sent a letter to Canadian healthcare professionals informing them of this new safety information. You may view this letter on the Canadian Web site of Boehringer Ingelheim (Canada) Ltd. (http://www.boehringer-ingelheim.ca/en/human_health/our_products.html) or on

the Health Canada's MedEffect™ Canada Web site (http://www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/prof/_2012/index-eng.php).

Managing marketed health product-related adverse reactions depends on health care professionals and consumers reporting them. Reporting rates determined on the basis of spontaneously reported post-marketing adverse reactions are generally presumed to underestimate the risks associated with health product treatments. Any case of serious or unexpected adverse reactions in patients receiving Pradax® should be reported to Boehringer Ingelheim (Canada) Ltd., or to Health Canada:

Boehringer Ingelheim (Canada) Ltd.
5180 South Service Rd,
Burlington, ON L7L 5H4
Tel: 1 (800) 263-5103 Ext. 84603.
http://www.boehringer-ingelheim.ca/en/contact.html

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Reporting Form and:
  - Fax toll-free to 1-866-678-6789, or
  - Mail to: Canada Vigilance Program
    Health Canada
    Postal Locator 0701E
    Ottawa, Ontario K1A 0K9

The Reporting Forms, postage paid labels, and Guidelines can be found on the MedEffect™ Canada Web site in the Adverse Reaction Reporting section.
http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php

For other health product inquiries related to this communication, please contact Health Canada at:
Marketed Health Products Directorate
E-mail: mhpd_dpsc@hc-sc.gc.ca
Telephone: 613-954-6522 Fax: 613-952-7738

A copy of this letter can be found on the Boehringer Ingelheim (Canada) Ltd., website at: http://www.boehringer-ingelheim.ca/en/human_health/our_products.html

Sincerely,
original signed by

DK Stauskas / for MK

Mathias Knecht, M.D.
Vice President, Medical and Regulatory Affairs
Boehringer Ingelheim (Canada) Ltd.

1. Pradax® Product Monograph, dated January 27, 2012
http://webprod3.hc-sc.gc.ca/dpd-bdpp/index-eng.jsp