PUBLIC COMMUNICATION
Health Canada Endorsed Important Safety Information on Pradaxa™/Pradax®

Boehringer Ingelheim

December 27, 2012

Subject: Pradaxa™/Pradax® (dabigatran etexilate): Not for use in patients with artificial heart valves

Boehringer Ingelheim (Canada) Ltd., in consultation with Health Canada, would like to inform you that based on recent information from a clinical study, Pradaxa™ (dabigatran etexilate), also known as Pradax®, must not be used in patients with artificial heart valves. If you do not have an artificial heart valve, this notice does not affect you.

Pradaxa™ is a blood thinner currently authorized for sale in Canada for the prevention of stroke and blood clots in patients who have a heart condition called atrial fibrillation (a type of irregular heartbeat), as well as for the prevention of blood clots in patients who have undergone hip or knee replacement surgery.[1] The labelling of Pradaxa™ is being strengthened to inform healthcare professionals that Pradaxa™ must not be used in patients with artificial heart valves.

The Product Monograph for Pradaxa™ will be revised as follows:

- Pradaxa™ is contraindicated (must not be used) in patients with a prosthetic (artificial) heart valve.

If you have an artificial heart valve and are currently treated with Pradaxa™ you should consult with your doctor. Do not stop taking Pradaxa™ without talking to your healthcare professional. Stopping use of your blood thinning medicine suddenly can put you at risk of developing a stroke or a blood clot.

Any questions or concerns about your situation or treatment with Pradaxa™ should be discussed with your healthcare professional.

Boehringer Ingelheim (Canada) Ltd. has sent a letter to Canadian physicians 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 Web site (http://www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/prof/_2012/index-eng.php).

Managing marketed health product-related side effects depends on health care professionals and consumers reporting them. Reporting rates determined on the basis of spontaneously reported post-marketing side effects are generally presumed to underestimate the risks associated with health product treatments. Any case of serious or unexpected side effect in patients receiving Pradaxa™ 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. 87233. http://www.boehringer-ingelheim.ca/en/contact.html

You can report any suspected side effect associated with the use of health products to Health Canada by:

Calling toll-free at 1-866-234-2345; or

Visiting MedEffect Canada's Web page on Adverse Reaction Reporting (http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php) for information on how to report online, by mail or by fax

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

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

1. Pradaxa™ Product Monograph, dated November 28, 2012
http://webprod5.hc-sc.gc.ca/dpd-bdpp/index-eng.jsp