## Health Canada Endorsed Important Safety Information on PrSTRATTERA® (atomoxetine)



October 21, 2011

Dear Health Care Professional

Subject:

Association of STRATTERA (atomoxetine) with Increased Blood Pressure

and Increased Heart Rate

Eli Lilly Canada Inc. in collaboration with Health Canada would like to inform you of important information from clinical studies regarding the risk of increased blood pressure and increased heart rate with the use of STRATTERA (atomoxetine). Atomoxetine is a selective norepinephrine reuptake inhibitor indicated for treatment of Attention-Deficit/Hyperactivity Disorder (ADHD) in children and adults.

Atomoxetine can increase heart rate and blood pressure. Please be aware of the following recommendations:

- Atomoxetine is contraindicated in patients with symptomatic cardiovascular diseases, moderate to severe hypertension or severe cardiovascular disorders whose condition would be expected to deteriorate if they experienced increases in blood pressure or in heart rate that could be clinically important.
- Atomoxetine should be used with caution in patients whose underlying medical conditions could be worsened by increases in blood pressure or heart rate, such as patients with hypertension, tachycardia, or cardiovascular or cerebrovascular disease.
- Atomoxetine should be used with caution in patients with congenital or acquired long QT syndrome or a family history of QT prolongation.
- Patients should be screened for pre-existing or underlying cardiovascular or cerebrovascular conditions before initiation of treatment with atomoxetine and monitored during the course of treatment.
- It is recommended that heart rate and blood pressure be measured in all patients before treatment with atomoxetine is started, after the dose is increased, and periodically during treatment to detect possible clinically important increases, particularly during the first few months of therapy.

A recent analysis of combined data from Eli Lilly sponsored controlled and uncontrolled clinical trials has indicated that in 8417 pediatric patients treated with atomoxetine, approximately 25% experienced an increase in blood pressure of 10 mmHg and 5-8% an increase of 20 mmHg while heart rate increased by 10 bpm in 33% of patients and by 20 bpm in 12% of patients. These increases could represent a risk for some patients. Increases in blood pressure and heart rate have been observed in similar proportion of adult ADHD patients.

This Dear Health Professional Letter (DHPL) is also posted on <a href="http://www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/index-eng.php">http://www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/index-eng.php</a>, and on <a href="http://www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/index-eng.php">http://www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/index-eng.php</a>, and on <a href="http://www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/index-eng.php">http://www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/index-eng.php</a>. and on <a href="http://www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/index-eng.php">http://www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/index-eng.php</a>. and on <a href="http://www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/index-eng.php">http://www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/index-eng.php</a>. and on <a href="http://www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/index-eng.php">http://www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/index-eng.php</a>.

The Canadian Product Monograph for STRATTERA has recently been revised to include these important new safety findings. A copy of the most up-to-date Product Monograph can be found at: http://webprod3.hc-sc.gc.ca/dpd-bdpp/index-eng.jsp

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 increases in blood pressure or heart rate or other serious or unexpected adverse reactions in patients receiving STRATTERA should be reported to Eli Lilly Canada Inc. or Health Canada.

Eli Lilly Canada Inc. Toronto, Ontario 1-888-545-5972

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<sup>TM</sup> Canada Web site in the <u>Adverse Reaction Reporting</u> section (http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php). The Reporting Form is also in the *Canadian Compendium of Pharmaceuticals and Specialties*.

For other health product inquiries related to this communication, please contact Health Canada at:

Lead Directorate: Marketed Health Products Directorate

E-mail: MHPD\_DPSC@hc-sc.gc.ca

Telephone: 613-954-6522

Fax: 613-952-7738

Sincerely

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Eli Lilly Canada Inc.