PUBLIC COMMUNICATION
Health Canada Endorsed Important Safety Information on CELEXA®
(citalopram hydrobromide)

January 30, 2012

Subject: Association of CELEXA® (citalopram hydrobromide; also marketed as generics) and abnormal heart rhythms

Lundbeck Canada, in collaboration with Health Canada, would like to inform patients and healthcare professionals that the antidepressant Celexa® (citalopram hydrobromide; also marketed as generics) should not be taken at doses of more than 40 mg a day. Higher doses can cause abnormal heart rhythms, based on the results of a research study.

Celexa® (citalopram hydrobromide) is used to treat depression and is available as 20 mg and 40 mg tablets.

- Celexa® (citalopram hydrobromide) should no longer be taken at doses greater than 40 mg a day.
- 20 mg per day is the maximum recommended dose for patients:
  - who are 65 years of age or older or
  - who have liver problems or
  - who are taking heartburn treatment called 'cimetidine' at the same time as Celexa®(citalopram hydrobromide).
- Celexa® (citalopram hydrobromide) should not be taken if you have a heart condition known as congenital long QT syndrome or if you have known QT interval prolongation, a change in the electrical conductivity of the heart.

High doses of Celexa® (citalopram hydrobromide) can cause changes to the electrical activity of your heart (called QT interval prolongation on the electrocardiogram [ECG]) that can lead to serious abnormal heart rhythms. These abnormal heart rhythms can be life threatening.

If you experience any symptoms of abnormal heart rhythms such as heart palpitations, dizziness, fainting, or seizures while you are taking Celexa® (citalopram hydrobromide), you should contact your health care professional immediately.

Before starting treatment with Celexa®(citalopram hydrobromide), you should tell your health care professional if you have had any heart problems, if you are taking other medications and if you have had low levels of potassium and/or magnesium in your blood.

If you are already taking Celexa® (citalopram hydrobromide), you should consult with your doctor to determine if you are taking the correct dose. Contact your doctor before stopping or reducing your dosage of citalopram. Symptoms such as dizziness, abnormal dreams, electric shock sensations, agitation, anxiety, difficulty concentrating, headache, migraine, tremor (shakiness), nausea, vomiting, sweating or other symptoms may occur after abruptly stopping or reducing the dosage of citalopram.

Lundbeck Canada has worked with Health Canada to include the new safety information regarding abnormal heart rhythms associated with high doses of Celexa® (citalopram hydrobromide; also marketed as generics) into the Canadian Product Monograph (the reference document that healthcare professionals use when prescribing a drug) and the Consumer Information leaflet. These documents can be found in the Health Canada Drug Product Database at http://www.hc-sc.gc.ca/dhp-mps/prodpharma/databasdon/index-eng.php or by contacting Lundbeck Canada, at 1 866 880-4636.

Lundbeck is also working closely with Health Canada to determine the possible need to include additional information about abnormal heart rhythms into the Cipralex® (escitalopram oxalate) Product Monograph. Cipralex® (escitalopram oxalate) is a drug related to Celexa® (citalopram hydrobromide).

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 abnormal heart rhythm or other serious or unexpected adverse reactions in patients receiving Celexa® (citalopram hydrobromide) should be reported to Lundbeck Canada or Health Canada.

Lundbeck Canada Inc.
1000 de la Gauchetière West
Suite 500
Montreal, Quebec H3B 4W5
Tel : 1 866 880-4636

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

Sincerely,

original signed by

Marie Gagné
Vice-President, Scientific Affairs