Health Canada Endorsed Important Safety Information on EXELON* PATCH

NOVARTIS

[2010/04/30]

Dear Health Care Professional,

Subject: **Serious adverse events related to medication errors/misuse of EXELON* PATCH (rivastigmine transdermal patch)**

Novartis Pharmaceuticals Canada Inc. ("Novartis"), in consultation with Health Canada, would like to inform you that serious adverse events including death, have occurred following rivastigmine overdose due to medication errors /misuse of EXELON* PATCH. Therefore, Novartis would like to remind you of the importance of the proper use and application of EXELON* PATCH (rivastigmine transdermal patch) and the need to instruct patients and caregivers on correct application techniques for the use of EXELON* PATCH[1].

The EXELON* PATCH Product Monograph, including the Consumer Information section (Part III of the Product Monograph), is being revised to further emphasize the following safety information:

- Healthcare providers should inform patients and caregivers on the proper use of rivastigmine patch prior to initiating therapy, and advise them to strictly follow instructions on patch usage;
- Only one transdermal patch should be applied per day to healthy skin on one of the recommended locations: the upper or lower back, or upper arm or chest;
- The previous day's patch **must be removed before** applying a new patch to a different skin location after 24 hours of use;
- The patch should not be cut into pieces;
- In case of overdose, all EXELON* transdermal patches should be immediately removed and the patient should be evaluated by a physician.

Overdose with rivastigmine resulting from medication errors and misuse of EXELON* PATCH has been reported in the post-marketing setting. As of July 31, 2009, a total of 129 cases of medication errors/misuse, including 2 cases with fatal outcomes, have been reported with EXELON* PATCH worldwide. Three Canadian cases of medication errors/misuse have been associated with EXELON* PATCH up to February 28, 2010. The most frequently reported causes of overdose are failure to remove the patch before applying a new patch and application of more than one patch at the same time. Healthcare professionals, caregivers, or the patients themselves have been involved in these errors.

The typical symptoms reported in association with overdose include nausea, vomiting, diarrhea, hypertension, hallucinations, salivation, sweating, respiratory depression and convulsions. Bradycardia and/or syncope may also occur. As with medication errors and misuse in general, serious medical outcomes, possibly including death, may occur if the medication errors and misuse are not corrected in a timely manner and properly managed. In case of overdose, all EXELON* transdermal patches should be

immediately removed and no further patch should be applied for the next 24 hours.

Please refer to the Overdosage section of the Canadian Product Monograph for EXELON* PATCH for additional details concerning the proper management of rivastigmine overdose.

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 overdose symptoms or other serious or unexpected adverse reactions in patients receiving EXELON* PATCH should be reported to Novartis Pharmaceuticals Canada Inc. or Health Canada at the following addresses:

Novartis Pharmaceuticals Canada Inc.
385 Bouchard blvd,
Dorval, Quebec, H9S 1A9
Phone: 1-800-363-8883 (Medical Information)

Any suspected adverse reaction can also be reported to:
Canada Vigilance Program
Marketed Health Products Directorate
HEALTH CANADA
Address Locator: 0701D
Ottawa, Ontario, K1A 0K9
Telephone: 613-957-0337 or Fax: 613-957-0335
CanadaVigilance@hc-sc.gc.ca

To report an Adverse Reaction, consumers and health professionals may call toll free:
Telephone: 1-866-234-2345
Fax: 1-866-678-6789

Postage paid labels, the Canada Vigilance Reporting Forms and the Adverse Reaction Reporting Guidelines can be found on the MedEffect™ Canada Web site in the Adverse Reaction Reporting section. The Reporting Form is also in the *Canadian Compendium of Pharmaceuticals and Specialties.*

http://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 (MHPD)
E-mail: MHPD_DPSC@hc-sc.gc.ca
Tel: 613-954-6522
Fax: 613-952-7738

To change your mailing address or fax number, contact Novartis Pharmaceuticals Canada Inc...

Should you have any questions or require additional information regarding the use of EXELON* PATCH (rivastigmine), please contact Novartis Pharmaceuticals Canada Inc., Medical Information Department at 1-800-363-8883.

Sincerely,

Jean-Marie Leclerc, M.D. FRCP(C)
Chief Scientific Officer and Senior Vice-President Clinical and Regulatory Affairs

*EXELON is a registered trademark

References:

[1.] In Canada, EXELON* PATCH is indicated for the symptomatic treatment of patients with mild to moderate dementia of the Alzheimer's type. EXELON* PATCH is available in two dosage strengths: EXELON* PATCH 5 (4.6 mg /24 hours) and EXELON* PATCH 10 (9.5 mg /24 hours). Treatment is started with EXELON* PATCH 5 (4.6 mg /24 hours). After a minimum of four weeks of treatment and if EXELON* PATCH 5 (4.6 mg/24 hours) is well tolerated according to the treating physicians, the daily dose should be increased to EXELON* PATCH 10 (9.5 mg /24 hours) which is the recommended maintenance dose.