

PUBLIC COMMUNICATION
Health Canada Endorsed Important Safety Information on
EXELON* PATCH



(2010/05/05)

Subject: Serious side effects related to medication error/incorrect use of EXELON* PATCH (rivastigmine transdermal patch)

Novartis Pharmaceuticals Canada Inc. ("Novartis"), in consultation with Health Canada, would like to remind you of the importance of the proper use of EXELON* PATCH (rivastigmine transdermal patch) and the symptoms associated with its overdose. EXELON* PATCH is used to treat people with mild to moderate Alzheimer's dementia.

The Canadian prescribing and consumer information for EXELON* PATCH is being revised to further emphasize the following safety information:

- Serious side effects including death, have occurred following rivastigmine overdose due to medication errors or incorrect use of EXELON* PATCH (such as wearing more than one patch at a time),
- Patients and their caregivers should ask their doctor or pharmacist to explain the proper use of EXELON* PATCH if they do not understand the instructions described under the Consumer Information leaflet;
- **ONLY ONE** 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* patches should be immediately removed and the patient should be evaluated immediately by a physician.

The most frequently reported causes of overdose are failure to remove the patch before applying a new patch and wearing 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, high blood pressure, hallucinations, salivation, sweating, slow and shallow breathing and seizures. Slow heart beat and fainting, that may be associated with malaise or falls, may also occur. Medication errors and misuse may cause serious medical outcomes, including death unless corrected 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 your Consumer Information leaflet included in the EXELON*

PATCH package 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: 0701E
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*.

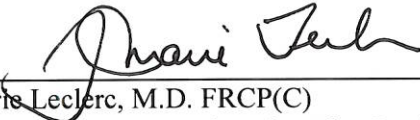
<http://hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>

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

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.