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Health Product InfoWatch

February 2015

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Domperidone
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REPORTING ADVERSE REACTIONS

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To receive the Health Product InfoWatch and notifications of health product advisories by email, subscribe to MedEffect™ e-Notice at www.health.gc.ca/medeffect.

ANNOUNCEMENT

Health Canada increases transparency on health product and other regulatory information

Health Canada has recently launched several initiatives to help make health product information easier to find and use:

- Health Canada has launched the [Drug and Health Product Register](#), a new web tool designed to provide Canadians with easy access to consumer-friendly information on medicines and vaccines in order to better ensure the health and safety of themselves and their families. Consumers and health professionals can access practical health product information including what a drug is used for, safety warnings and common side effects. They can also see what adverse reactions have been reported to Health Canada, and report a side effect quickly and securely using the online application.

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This monthly publication is intended primarily for healthcare professionals and includes information on pharmaceuticals, biologics, medical devices and natural health products. It provides a summary of key health product safety information published in the previous month by Health Canada, as well as a selection of new health product safety information meant to raise awareness. New information contained in this issue is not comprehensive but rather represents a selection of clinically relevant items warranting enhanced dissemination.

Canada

MONTHLY RECAP OF HEALTH PRODUCT SAFETY INFORMATION

The following is a list of [health product advisories](#) as well as [summaries of completed safety reviews](#) published in January 2015 by Health Canada.

Aricept (donepezil)

[Summary Safety Review](#)
[Information Update](#)

This safety review evaluated the potential risk of rhabdomyolysis and/or neuroleptic malignant syndrome (NMS) associated with donepezil. The available evidence suggests that rhabdomyolysis and/or NMS may occur with donepezil use. The prescribing information for Aricept and Aricept RDT has been updated with this safety information and manufacturers of generic products will also update their product information. Health Canada has also communicated this risk to Canadians.

Atypical Antipsychotics

[Summary Safety Review](#)

This safety review evaluated the potential risk of liver failure associated with atypical antipsychotics. The risk of liver failure is currently included in the prescribing information for clozapine and olanzapine-containing products. With regard to the other atypical antipsychotics, most of the evidence gathered involved quetiapine. Health Canada has determined that the overall benefits of quetiapine continue to outweigh the risks, when used as recommended, and has communicated on quetiapine and the risk of acute liver failure. This risk has been added to the prescribing information of Seroquel (quetiapine). Manufacturers of generic versions will also update their prescribing information.

Domperidone

[Summary Safety Review](#)
[Dear Healthcare Professional](#)
[Letter](#)
[Public Communication](#)

This safety review evaluated the potential risk of serious ventricular arrhythmias and sudden cardiac death with domperidone and found evidence suggesting an increased risk. Health Canada has communicated to healthcare professionals and the public on this risk and has requested that manufacturers update the prescribing information for domperidone products to include a new recommended maximum daily dose, new restrictions of use and stronger warnings. Health Canada has also asked the Drug Safety and Effectiveness Network to conduct a study on domperidone-related heart effects in patients with Parkinson's disease.

Metoclopramide

[Summary Safety Review](#)
[Dear Healthcare Professional](#)
[Letter](#)
[Public Communication](#)

This safety review evaluated the potential risk of extrapyramidal symptoms (EPS) in children taking the recommended daily dose of metoclopramide. The safety review showed that EPS can occur in children treated with metoclopramide at the recommended daily dose of 0.5 mg/kg/day. Health Canada has communicated to healthcare professionals and the public on this risk and has worked with the manufacturers of metoclopramide to incorporate this safety information into the prescribing information. Metoclopramide is now contraindicated in children below one year of age. This medication should also not be used in children greater than one year of age unless the expected benefits clearly outweigh the possible risks.

Prolia (denosumab)

[Summary Safety Review](#)

This safety review evaluated the potential risk of cancer associated with denosumab. It has been determined that there is not enough evidence at this time to suggest an association. Health Canada will continue its monitoring of adverse reaction information involving denosumab.

Quarantined Health Products

[Information Update](#)

At Health Canada's request, Canadian importers have agreed to quarantine health products made with active pharmaceutical ingredients (APIs) from Sri Krishna Pharmaceuticals Ltd. in Hyderabad, India, due to data integrity concerns. Health Canada has compiled an initial list of products affected by the quarantine.

Unlicensed Home Test Kits

[Information Update](#)

Health Canada is reminding Canadians about the risks of purchasing unlicensed home-use diagnostic test kits following recent compliance and enforcement actions undertaken by the Department.

Vascular Endothelial Growth Factor Receptor Inhibitors

[Summary Safety Review](#)

This safety review evaluated the potential risk of thrombotic microangiopathy (TMA) associated with the use of vascular endothelial growth factor (VEGF) receptor inhibitors. Although the risk of TMA is recognized for certain VEGF receptor inhibitors (sunitinib and pazopanib), there is insufficient information at this time to update the prescribing information for all VEGF receptor inhibitors. Health Canada will continue to monitor adverse reaction information involving VEGF receptor inhibitors to identify and assess potential harms.

Foreign product alerts issued in the previous month by Health Canada are available in the [Recalls and Safety Alerts Database](#).

Continued from page 1:

ANNOUNCEMENT

- The [list of new health product safety reviews](#) provides early notice that Health Canada is evaluating a possible new safety concern involving a health product available in Canada. The list of reviews and the [summaries of completed safety reviews](#) complement other safety-related information to help Canadians make informed medication choices.
- The [list of drug products that have paediatric information on their labels](#) gives prescribers and caregivers easier access to this information in one central location. It includes prescription drugs and biologics – including vaccines – that are authorized for use in children and/or that include information about paediatric safety or effectiveness in their labelling.

For more information, please consult the recent [announcement](#) about these initiatives.

HELPFUL LINKS

- [MedEffect™ Canada](#)
- [Recalls and Safety Alerts Database](#)
- [Summary Safety Reviews](#)
- [Canada Vigilance Adverse Reaction Online Database](#)
- [Drug Product Database](#)
- [Canadian Drug Shortage Database](#)
- [The Drug and Health Product Register](#)

Suggestions?

Your comments are important to us. Let us know what you think by reaching us at InfoWatch_InfoVigilance@hc-sc.gc.ca

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Adverse reactions (ARs) to health products are considered to be suspicions, as a definite causal association often cannot be determined. Spontaneous reports of ARs cannot be used to estimate the incidence of ARs because ARs remain underreported and patient exposure is unknown.

Due to time constraints relating to the production of this publication, information published may not reflect the most current information.

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