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Health Product InfoWatch

December 2019

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REPORTING ADVERSE REACTIONS

Canada Vigilance Program
 Online: [Adverse Reaction and Medical Device Problem Reporting](#)
 Telephone: 1-866-234-2345
 Fax or mail: Form available online

SUBSCRIBE

To receive the Health Product InfoWatch and notifications of health product advisories electronically, subscribe to [MedEffect™ e-Notice](#) or to [MedEffect™ Canada RSS feeds](#).

ANNOUNCEMENT

Mandatory reporting by hospitals, December 16, 2019

On December 16, 2019, new mandatory reporting requirements for hospitals came into force. These regulations will help to improve the reporting of serious adverse drug reactions and medical device incidents. It is a key part of implementing the *Protecting Canadians from Unsafe Drugs Act* (Vanessa's Law).

Improved reporting will help Health Canada better monitor the safety and effectiveness of products once they are on the Canadian market. Under the regulations, hospitals will be required to report to Health Canada all serious adverse drug reactions and medical device incidents within 30 days of being documented at the hospital.

Health Canada will continue to offer outreach, education and feedback on the reporting requirements to support hospitals and promote compliance of the new regulations.

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.

MONTHLY RECAP OF HEALTH PRODUCT SAFETY INFORMATION

The following is a list of [health product advisories](#), [type I recalls](#) as well as [summaries of completed safety reviews](#) published in November 2019 by Health Canada.

<p>PregVit and PregVit folic 5</p> <p>Advisory Drug recall</p>	<p>Certain lots of PregVit and PregVit folic 5 vitamin-mineral supplements were recalled because blister packages may contain all pink (morning) tablets instead of the correct combination of pink (morning) and blue (evening) tablets. Duchesnay Inc. estimates the issue affects a very small number of products in certain lots and not all products (see table in the Advisory). There are no quality, safety or effectiveness concerns with the tablets themselves, but there is the potential that patients may not take the proper combination of pink and blue tablets if they have received products impacted by the packaging error.</p>
<p>Tamoxifen</p> <p>Information Update</p>	<p>Health Canada provided an update on the supply of tamoxifen and information on efforts to resolve the national shortage as quickly as possible. Current shortage information can be accessed through the Drug Shortages Canada website.</p>
<p>Uloric (febuxostat)</p> <p>Health Professional Risk Communication</p>	<p>Results from a post-market clinical study found an increased risk of cardiovascular fatal outcomes in patients with gout and known cardiovascular disease treated with Uloric, when compared to those treated with allopurinol. The Canadian product monograph for Uloric has been updated to include a revised indication for use and safety information, including a new <i>Serious Warnings and Precautions</i> box with regard to increased risk of cardiovascular death.</p>
<p>Unauthorized health products</p> <p>Multiple unauthorized health products Products sold by Dutta Health Centre-Ayurvedic Clinic in B.C.</p>	<p>Health Canada advised Canadians about various unauthorized health products being sold at retail locations across Canada or online that may pose serious health risks.</p>

NEW HEALTH PRODUCT SAFETY INFORMATION

The following topics have been selected to raise awareness and, in some cases, to stimulate reporting of similar adverse reactions.

CASE REPORT

Recent Canadian or international cases are selected based on their seriousness, frequency of occurrence or the fact that the reactions are unexpected. Case reports are considered suspicions and are presented to stimulate reporting of similar suspected adverse events.

Interaction between polyethylene glycol laxative and starch-based thickener

Key points:

- Health Canada received a report of a possible aspiration of a mixture of polyethylene glycol (PEG) and a starch-thickened liquid.
- The addition of PEG to a liquid that has been thickened with a starch-based thickener results in a decrease in liquid viscosity.
- Patients with dysphagia who are given a liquid with decreased viscosity are at risk of aspiration.

Health Canada received a report of a possible aspiration of a mixture of polyethylene glycol 3350 (PEG) and a thickened liquid in an 88-year old male patient.

The patient was admitted to hospital for the treatment of multiple medical issues. Throughout the admission, PEG laxative powder (which must be dissolved in about 250 mL of liquid before administration) was given to the patient at a dose of 17 g daily for the treatment of chronic constipation. At some point during his hospital stay, the patient presented with difficulty swallowing. As a result, he was started on a thickened liquid diet. The PEG laxative powder was mixed in a starch-based thickened liquid and administered to the patient. On the second consecutive day of administration, the patient appeared to aspirate the mixture. He died a couple of hours after the suspected aspiration.

Thickening of liquids to make them easier to swallow is a key part of dysphagia management for many patients, such as older patients and patients with neurological diseases.¹ Constipation is also often a common concern for this patient population.²

Certain patients on a thickened liquid diet for dysphagia may also receive a PEG-based laxative, as it is one of the treatment options for constipation.² The interaction between PEG and starch-based thickeners results in a decrease in liquid viscosity (thickness), which increases the risk of choking and aspiration in patients who require thickened liquids.³

The case described above has been reviewed and published by the Institute for Safe Medication Practices Canada (ISMP Canada).³ A decrease in the viscosity of starch-thickened liquids when mixed with PEG has also been reported in the medical literature.⁴ The authors recommend to consider the use of laxatives other than PEG in patients who require starch-thickened liquids. Alternatively, it was also suggested that PEG may be compatible with xanthan gum-based thickeners, although further research is needed.

Health Canada is working with the manufacturers of PEG-containing products to update the product labels to include a warning of this interaction.

References

1. Wirth R, Dziewas R, Beck AM et al. Oropharyngeal dysphagia in older persons – from pathophysiology to adequate intervention: a review and summary of an international expert meeting. *Clin Interv Aging* 2016;11:189–208.
2. American Gastroenterological Association. American Gastroenterological Association medical position statement on constipation. *Gastroenterology* 2013;144(1):211-7. (accessed 2019 November 21)
3. Potentially harmful interaction between polyethylene glycol laxative and starch-based thickeners. *ISMP Canada Safety Bulletin* 2019; 19(7):1-3. (accessed 2019 November 21)
4. Carlisle BJ, Craft G, Harmon JP, et al. PEG and thickeners: A critical interaction between polyethylene glycol laxative and starch-based thickeners. *J Am Med Dir Assoc* 2016;17(9):860-1.

HELPFUL LINKS

- [MedEffect™ Canada](#)
- [Recalls and Safety Alerts Database](#)
- [New Safety and Effectiveness Reviews](#)
- [Canada Vigilance Adverse Reaction Online Database](#)
- [Drug Product Database](#)
- [Medical Devices Active Licence Listing](#)
- [Licensed Natural Health Products Database](#)
- [The Drug and Health Product Register](#)
- [Drug Shortages Canada](#)
- [Annual trends for adverse reaction case reports and medical device problem incidents](#)
- [Stop Illegal Marketing of Drugs and Devices](#)

Suggestions?

Your comments are important to us. Let us know what you think by reaching us at HC.infowatch-infovigilance.SC@canada.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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