



Health Product InfoWatch

March 2024

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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](#).

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.

ANNOUNCEMENT

Canadian vaccine safety surveillance reports following immunization with seasonal influenza vaccines, 2021–2022

In February 2024, the Public Health Agency of Canada and Health Canada jointly published an article in the [Canada Communicable Disease Report](#) on seasonal influenza vaccines distributed during the 2021/2022 influenza season. This article summarized adverse events following immunization (AEFI) reports which were submitted to the Canadian Adverse Event Following Immunization Surveillance System and the Canada Vigilance Database.

The findings from the analysis were consistent with the known safety profile of influenza vaccines distributed during the 2021/2022 influenza season. The majority of reports were non-serious, with the most common AEFI symptoms occurring at the vaccination site or systemic symptoms that were self-limiting.

The full article can be accessed at the following link :

[Canadian vaccine safety surveillance reports following immunization - Canada.ca](#)

MONTHLY RECAP OF HEALTH PRODUCT SAFETY INFORMATION

The following is a list of [health product advisories](#), [type I drug recalls](#) and [summaries of completed safety reviews](#) published in February 2024 by Health Canada.

Amiodarone Summary Safety Review	This safety review evaluated the risk of primary graft dysfunction following heart transplantation with pre-transplant use of amiodarone. Health Canada’s review found a possible link. Health Canada will work with the manufacturers to update the Canadian product monographs of amiodarone-containing products to include the risk of primary graft dysfunction following heart transplantation.
APO-Mometasone nasal spray Advisory	Apotex Inc. recalled 2 lots of APO-Mometasone nasal spray due to possible bacterial contamination with <i>Burkholderia cepacia</i> complex.
Audrina 28 birth control pills Advisory	Certain lots of Audrina 28 birth control pills contain day-of-the-week stickers that have a misprint that could lead to confusion around when to take the medication. This issue does not affect the safety or quality of the pills themselves.

<p>Ibrance (palbociclib)</p> <p>Summary Safety Review</p>	<p>This safety review evaluated the risk of venous thromboembolism associated with Ibrance. Health Canada’s review found a probable link. Health Canada is working with the manufacturer to update the Canadian product monograph for Ibrance to include the risk of venous thromboembolism.</p>
<p>Paclitaxel-coated devices</p> <p>Health Product Risk Communication</p>	<p>Health Canada further assessed the risk of increased mortality associated with the use of paclitaxel-coated devices used to treat peripheral arterial disease. Based on all available clinical evidence, Health Canada did not identify an increased risk of mortality associated with the use of these devices when used in accordance with the licensed indications.</p>
<p>Unauthorized health products</p> <p>Counterfeit erectile dysfunction drugs seized from two convenience stores in Toronto</p> <p>Unauthorized sexual enhancement products</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>

Helpful links

- [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 Portal](#)
- [Drug Shortages Canada](#)
- [Medical Device Shortages](#)
- [COVID-19 Vaccines and Treatments Portal](#)

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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