Health Canada Santé Canada

Canada

# Health Product InfoWatch

February 2023

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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.

## HEALTH PRODUCTS MENTIONED IN THIS ISSUE

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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.

## DID YOU KNOW?

The COVID-19 vaccines and treatments portal provides up-to-date information related to Canadian authorized vaccines and treatments for COVID-19. For each product, you can consult the "For health care professionals" tab to find the most recent information, including, when applicable:

- Product monographs
- Interim product labels for vials, cartons, blisters, etc.
- Authorization terms and conditions
- Links to any safety advisories
- Regulatory announcements
- Information on storage, handling and administration

## DRUG AND VACCINE AUTHORIZATIONS AND COMMUNICATIONS FOR COVID-19

*New information and recent communications related to authorized COVID-19 vaccines and treatments are highlighted in this section.*

### Spikevax Bivalent (Original / Omicron BA.1) (elasomeran/imelasomeran)

On February 17, 2023, Health Canada authorized the extension of the indication of Spikevax Bivalent (Original / Omicron BA.1) (elasomeran/imelasomeran) to include children (6 to 17 years of age). Spikevax Bivalent (elasomeran/imelasomeran) Original/Omicron mRNA vaccine is now indicated as a booster dose for active immunization against COVID-19 caused by SARS-CoV-2 in individuals 6 years of age and older.

Authorization with terms and conditions

## ANNOUNCEMENT

### Tubed medical devices and children

Health Canada has published safety information on tubed medical devices and children. Types of medical tubing include: enteral feeding devices, nasal cannulas and oxygenation devices, and intravenous delivery devices. Tubing from medical devices can accidentally wrap around a child and may cause entanglement, strangulation or death.

For more information on these devices and how to manage the risks, please visit Health Canada's tubed medical devices and children webpage.

## MONTHLY RECAP OF HEALTH PRODUCT SAFETY INFORMATION

*The following is a list of health product advisories, type I recalls and summaries of completed safety reviews published in January 2023 by Health Canada.*

*For health product advisories related to COVID-19 vaccines and treatments, please see the Drug and vaccine authorizations and communications for COVID-19 section.*

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| **Cephalosporins**<br><br>Summary Safety Review | This safety review evaluated the risk of seizures associated with the use of cephalosporins. Health Canada's review concluded that there may be a link. At the time of the safety review, the risk of seizures was already included in the Canadian product monographs for some cephalosporins. Health Canada will work with the manufacturers to update the Canadian product monographs for the cephalosporins that do not already include this risk. |
| **Finasteride-containing products**<br><br>Summary Safety Review | This safety review evaluated the risk of suicide, suicidal ideation and self-injury associated with the use of finasteride-containing products. Health Canada's review of the available information found a possible link between the use of finasteride and the risks of suicidal ideation and self-injury. At this time, there is not enough information to establish a link between the use of finasteride and the risk of suicide. Health Canada is working with the manufacturers to update the Canadian product monographs for finasteride-containing products to strengthen the warning statements on the risks of suicidal ideation and self-injury, and to include information about patient screening for psychiatric risk factors prior to starting treatment, as well as continuous patient monitoring during and after stopping treatment. |
| **Ruzurgi (amifampridine)**<br><br>Health Product Risk Communication | On January 10, 2023, following a Federal Court of Appeal decision, the June 24, 2021 decision of the Minister of Health on the application of the data protection provisions was restored, and a new Notice of Compliance was issued for Ruzurgi (amifampridine) in accordance with the *Food and Drug Regulations*. Ruzurgi (amifampridine) is therefore authorized for sale again in Canada. |
| **Third generation aromatase inhibitors**<br><br>Summary Safety Review | This safety review evaluated the risk of tendonitis, tenosynovitis and tendon rupture associated with the use of third generation aromatase inhibitors (anastrozole-, exemestane-, letrozole- containing products). Health Canada's review concluded that there is likely a link between the use of third generation aromatase inhibitors and the risks of tendonitis and tenosynovitis. A link with tendon rupture could not be ruled out. Health Canada is working with the manufacturers to update the Canadian product monographs to include these risks. |

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|---|---|
| **Unauthorized health products**<br><br>Unauthorized products may pose serious health risks<br>Unauthorized health products removed from sale | Health Canada advised Canadians about various unauthorized health products being sold at retail locations across Canada or online that may pose serious health risks. |

# NEW HEALTH PRODUCT SAFETY INFORMATION

*The following topics have been selected to raise awareness and encourage reporting of adverse reactions.*

## Safety brief

### Opioids and mental health disorders

**Key messages for healthcare professionals:**

- Opioids should be used with particular care in patients with a history of mental health disorders including, but not limited to major depression, anxiety and alcohol and drug abuse.
- Concerns about abuse, addiction, or diversion should not prevent the proper management of pain.
- Efforts should be made to promote appropriate opioid prescribing practices that balance the uncertainties between the benefits and risks of opioid medications based on the individual needs of each patient.[1]

Opioid medication can be prescribed to help manage pain. While opioids can offer benefits, they also come with potential risks.

A recent analysis suggests that opioid pain relief medication use and mood disorders often co-occur among adults.[2]

The analysis also suggests that some adults who reported taking opioid medication, also reported not taking it as directed or for reasons other than pain relief.[2] This occurrence was higher among adults with a diagnosis of a mood disorder.

Between January 1, 2008 and June 30, 2022, Health Canada received hundreds of adverse reaction reports of drug abuse and dependence associated with opioids marketed in Canada, in patients with a reported medical history of a mental health disorder.

Health Canada is working with Canadian manufacturers of opioids to update their respective product monographs with information on opioid use in patients with a history of mental health disorders. Updates will be made to the *Warnings and Precautions* and *Patient Medication Information* sections of the Canadian product monographs (CPM).[*] Health Canada will continue to monitor safety information involving opioids, as it does for all health products on the Canadian market, to identify and assess potential harms.

For further information, including links to guidelines for healthcare professionals, visit Health Canada's Opioids web page.

**References**


1. Health Canada's Statement on Opioids and Pain Management. Health Canada; 2022. Accessed January 31, 2023.
2. Opioid pain relief medication use and mood disorders in Canada: a descriptive analysis of Canadian Community Health Survey data. Public Health Agency of Canada; 2022. Accessed January 13, 2023.


* At the time of this publication, CPM updates have been completed for some opioid products. As part of the class update, Health Canada continues to work with manufacturers to update the remaining opioid CPMs to reflect this safety information.

## Product monograph update

*The following safety labelling update, which was recently made to the Canadian product monograph, has been selected for your awareness. A complete list of safety labelling updates for pharmaceuticals is available on Health Canada's Product monograph brand safety updates page. Canadian product monographs can be accessed through Health Canada's Drug Product Database.*

### Daurismo (glasdegib)

The *Warnings and Precautions* and *Dosage and Administration* sections of the Canadian product monograph for Daurismo have been updated with the risk of **muscle-related adverse reactions and dose modifications and management recommendations for creatine kinase elevations and muscle-related adverse reactions**, respectively.

**Key messages for healthcare professionals:**[1]

- In a randomized study, muscle spasms were observed in 15% of patients treated with Daurismo in combination with low-dose cytarabine.
- Inform all patients starting treatment with Daurismo of the risk of muscle-related adverse reactions. Instruct them to promptly report any unexplained muscle pain, tenderness or weakness occurring during treatment with Daurismo or if symptoms persist after discontinuing treatment.
- Monitor serum creatine kinase (CK) levels prior to and during treatment with Daurismo. Management of high-grade CK elevation based on current standards of medical practice and following appropriate treatment guidelines is recommended.
- Follow the new dose modification and management recommendations in the Daurismo Canadian product monograph (Section 4.2: Recommended Dose and Dosage Adjustment) for CK elevations and muscle-related adverse reactions.

**Reference**


1. *Daurismo (glasdegib)* [product monograph]. Kirkland (QC): Pfizer Canada ULC, 2022.

## 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
- Medical device shortages: List of shortages and discontinuations
- Stop Illegal Marketing of Drugs and Devices
- List of drugs for exceptional importation and sale
- Coronavirus disease (COVID-19)
- COVID-19 list of authorized drugs, vaccines and expanded indications
- COVID-19 vaccines and treatments portal
- Reported side effects following COVID-19 vaccination in Canada

## 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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