Health Canada Santé Canada

Canada

Health Product InfoWatch

July 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.

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 and summaries of completed safety reviews published in June 2023 by Health Canada.

Idhifa (enasidenib mesylate) Health Product Risk Communication	Idhifa failed to demonstrate improved overall survival in adult patients with late stage acute myeloid leukemia and an isocitrate dehydrogenase-2 mutation versus conventional care regimens in a Phase 3 confirmatory study evaluating efficacy and safety. Idhifa was withdrawn from the Canadian market on June 30, 2023. Apply to Health Canada's Special Access Program to request Idhifa for patients who require continued treatment.
JAMP Venlafaxine XR Advisory	JAMP Pharma Corporation recalled mislabelled bottles from one lot of Venlafaxine extended release capsules after one bottle labelled to contain 37.5 mg capsules was found to contain 150 mg capsules. Only the mislabelled bottles were recalled.
Soliris (eculizumab) Summary Safety Review	This safety review evaluated the risk of drug-induced liver injury associated with Soliris (eculizumab). Health Canada's review did not find sufficient evidence to support a link. Health Canada will continue to monitor safety information involving Soliris.
Unauthorized health products Unauthorized sexual enhancement products	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

mRNA COVID-19 vaccines (Comirnaty and Spikevax) and the risk of heavy menstrual bleeding

In Canada, authorized monovalent mRNA COVID-19 vaccines include Comirnaty (Pfizer-BioNTech COVID-19 Vaccine) and Spikevax (COVID-19 Vaccine Moderna). Both vaccines are indicated for active immunization against COVID-19 in individuals 6 months of age and older.[1,2]

Health Canada reviewed the risk of heavy menstrual bleeding (HMB) following vaccination with Comirnaty or Spikevax. The following descriptive terms, which traditionally have been used to characterize HMB patterns, were considered: menorrhagia (heavy cyclic vaginal bleeding with blood loss of more than 80 mL per cycle), menometrorrhagia (heavy irregular vaginal bleeding) and polymenorrhagia (heavy prolonged cycles consistently lasting more than 8 days). The scope of the review included monovalent mRNA vaccines (Comirnaty and Spikevax), as data were limited with the bivalent vaccines (Comirnaty Original & Omicron BA.4/BA.5, Spikevax Bivalent, Spikevax Bivalent Original / Omicron BA.4/5) at the time of the review.

Health Canada's review of the available information, which included data from clinical trials, Canadian and international post-market reports and scientific literature, found no scientific or medical evidence that vaccination with monovalent mRNA vaccines increases the risk of HMB.

The Canadian product safety information for Comirnaty and Spikevax accurately reflects the current evidence and accounts for the evolving nature of the data. No updates to the Canadian product monographs for Comirnaty and Spikevax about HMB are planned further to this review.

Healthcare professionals and vaccine recipients are encouraged to report adverse reactions suspected of being associated with COVID-19 vaccines. Health Canada will continue to monitor the safety of all COVID-19 vaccines and will take appropriate action should new health risks be identified.

References:

1. *Comirnaty (COVID-19 Vaccine, mRNA)* [product monograph]. Mainz (Germany): BioNTech Manufacturing GmbH; 2023.
2. *Spikevax (Elasomeran mRNA vaccine)* [product monograph]. Cambridge (MA): Moderna TX, Inc.; 2023.

Notice of market authorization with conditions

*A Notice of Compliance with Conditions (NOC/c) is a form of market authorization with conditions granted to a product on the basis of **promising** evidence of clinical effectiveness following review of the submission by Health Canada. Communicating a NOC/c is intended to raise awareness on the details of the drug and the type of authorization granted.*

Healthcare professionals are encouraged to report to Health Canada any adverse reactions suspected of being associated with marketed health products, including drugs authorized under the NOC/c policy.

The content of these notices reflects current information at the time of publication. Conditions associated with the NOC/c will remain until they have been fulfilled and authorized by Health Canada. For the most up-to-date information, consult Health Canada's NOC database.

Akeega (niraparib and abiraterone acetate): Authorization with conditions

Health Canada has issued a Notice of Compliance, under the NOC/c policy, for Akeega, 100 mg or 50 mg niraparib (as niraparib tosylate) and 500 mg abiraterone acetate, tablets. Akeega is indicated for the treatment of adult patients with deleterious or suspected deleterious *BRCA* mutated (germline and/or somatic) metastatic castration resistant prostate cancer, who are asymptomatic/mildly symptomatic, and in whom chemotherapy is not clinically indicated. Patients must have confirmation of *BRCA* mutation before Akeega treatment is initiated. Patients should be advised of the conditional market authorization for this indication.

For the complete prescribing information and information available for patients/caregivers, please consult the Akeega Canadian product monograph. The product monograph can be accessed through Health Canada's Drug Product Database, the Janssen Inc. website or by contacting Janssen Inc. at 1-800-567-3331 or 1-800-387-8781. Contact the company for a copy of any references, attachments or enclosures.

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 Portal
- 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)
- Drug and vaccine authorizations for 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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