Health Canada Santé Canada

Canada

Health Product
InfoWatch

December 2022

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REPORTING ADVERSE REACTIONS

Canada Vigilance Program
Online: Adverse Reaction and Medical Device Problem Reporting
Telephone: 1-866-234-2345
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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.

CORONAVIRUS DISEASE (COVID-19)

For the most up-to-date information on COVID-19, please visit the Government of Canada Coronavirus disease (COVID-19) Web site **Canada.ca/coronavirus**, which includes a dedicated section for healthcare professionals and for the health product industry.

The COVID-19 vaccines and treatments portal provides information for consumers, healthcare professionals and researchers on vaccines and treatments authorized for COVID-19.

For information about adverse events following immunization that individuals have reported after receiving a COVID-19 vaccine in Canada, new safety signals or other safety updates, please visit the COVID-19 vaccine safety in Canada webpage.

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.

Comirnaty Original & Omicron BA.4/BA.5 Bivalent Vaccine (COVID-19 mRNA vaccine, Bivalent)

On December 9, 2022, Health Canada authorized a new formulation of the bivalent vaccine, Comirnaty Original & Omicron BA.4/BA.5, as a booster dose for active immunization against COVID-19 caused by SARS-CoV-2, for use in children 5 to less than 12 years of age.

In order to provide rapid access to the new formulation, Pfizer Canada ULC will distribute product vials and cartons labelled in English-only with the name "Pfizer-BioNTech COVID-19 Vaccine, Bivalent Original and Omicron BA.4/BA.5" for a period of time. Important Canadian-specific information is absent from these labels.

Comirnaty Original & Omicron BA.4/BA.5 bivalent vaccine (DIN 02533197) has the same **ORANGE CAP** and **ORANGE LABEL BORDER** as monovalent Comirnaty (COVID-19 Vaccine, mRNA) 10 mcg/0.2 mL (DIN 02522454). To avoid medication errors, pay careful attention to the vial and carton label.

Health Product Risk Communication
Authorization with terms and conditions

Nuvaxovid COVID-19 Vaccine

On December 6, 2022, Health Canada authorized the extension of the Nuvaxovid COVID-19 Vaccine indication to include active immunization to prevent COVID-19 caused by SARS-CoV-2 in adolescents 12 to 17 years of age.

Authorization with terms and conditions

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 November 2022 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.

0.9% Sodium Chloride Injection, USP and Lactated Ringer's Injection, USP Type 1 drug recall	Intravenous bags of Baxter Corporation 0.9% Sodium Chloride Injection, USP and Lactated Ringer's Injection, USP have been recalled as the bags in the affected lots may be leaking.
Allergenic Extract Non Pollens Type 1 drug recall (2022-11-15) Type 1 drug recall (2022-12-14)	Certain lots of Allergenic Extract Non Pollens – Peanut were recalled as the affected lots may result in a false negative for skin test (peanut allergy).
Janus Kinase (JAK) Inhibitors Health Product Risk Communication Advisory Summary Safety Review	The final results of a clinical trial conducted with Xeljanz showed higher risks of major adverse cardiovascular events (MACE), thrombosis, malignancy, serious infections and fatal events, compared to tumour necrosis factor inhibitors (TNFi), in rheumatoid arthritis (RA) patients. Furthermore, preliminary results from a retrospective observational study suggest Olumiant is associated with higher risks of MACE and thrombosis when compared to TNFi in RA patients. Based on these safety findings and similar mechanisms of action, Health Canada cannot rule out the risks of MACE, thrombosis (including fatal events) and malignancies for other JAK inhibitors (Cibinqo, Inrebic, Jakavi, Olumiant, and Rinvoq). As a precautionary measure, Health Canada is working with the manufacturers to update and align the information about these risks in the product monographs for JAK inhibitors. Health Canada has also communicated this information to Canadians.
Standard synthetic mid-urethral slings Summary Safety Review	This safety review evaluated the long-term (at or beyond 5 years) safety and effectiveness of standard synthetic mid-urethral slings (SMUS) used for the treatment of stress urinary incontinence. Health Canada's review of the available information concluded that there is no new or increased risk of complications associated with the long-term (at or beyond 5 years) use of SMUS, and the risk of developing chronic pain and/or mesh erosion is lower over the longer term (after 5 or more years). Health Canada will continue to monitor safety

	information involving synthetic vaginal surgical mesh devices to identify and assess potential new harms.
Tums Peppermint Regular Strength tablets Advisory	GlaxoSmithKline Consumer Healthcare ULC recalled one lot of Tums Peppermint Regular Strength (500 mg) tablets after some tablets were found to contain fragments of fibreglass and other material, including paper and aluminum foil. The product is sold in a package of three rolls containing 12 tablets each, and was distributed across Canada starting on October 25, 2022.
Unauthorized health products Unlicensed ozone saunas	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.

Product monograph updates

The following safety labelling updates, which were recently made to the Canadian product monographs, have 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.

Hydrochlorothiazide-containing products

The *Warnings and Precautions*, *Adverse Reactions*, and *Patient Medication Information* sections of the Canadian product monographs for hydrochlorothiazide-containing products* have been, or will be, updated with the risk of **acute respiratory distress syndrome**.

Key messages for healthcare professionals:

- Very rare, but severe cases of acute respiratory toxicity, including acute respiratory distress syndrome (ARDS), have been reported in patients taking hydrochlorothiazide. Pulmonary edema typically develops within minutes to hours after hydrochlorothiazide intake. At the onset, symptoms include dyspnea, fever, pulmonary deterioration and hypotension.
- Hydrochlorothiazide should not be administered to patients who previously experienced ARDS following hydrochlorothiazide intake.
- Hydrochlorothiazide should be withdrawn and appropriate treatment given if diagnosis of ARDS is suspected.

* At the time of publication, not all the Canadian product monographs have been updated. Updates for remaining hydrochlorothiazide-containing products are ongoing.

Valtrex (valacyclovir)

The *Warnings and Precautions*, *Adverse Reactions (Post-Market Adverse Reactions)*, and *Patient Medication Information* sections of the Canadian product monograph for Valtrex have been updated with the risk of **drug reaction with eosinophilia and systemic symptoms (DRESS)**.

Key messages for healthcare professionals:[1]

- DRESS has been reported in association with valacyclovir treatment. DRESS is a serious skin reaction that may affect one or more organs and can be life-threatening or fatal.
- Patients should be monitored closely for skin reactions and advised of the signs and symptoms of DRESS, including fever, severe rash, peeling skin, facial edema, lymphadenopathy, flu-like feeling, jaundice, dyspnea, dry cough, chest pain or discomfort, dehydration, and eosinophilia.
- If signs and symptoms suggestive of DRESS appear, valacyclovir should be withdrawn immediately and an alternative treatment considered, as appropriate.
- If a patient has developed DRESS with the use of valacyclovir, treatment with valacyclovir must not be restarted in this patient at any time.

Reference

1. *Valtrex (valacyclovir) [product monograph]*. Mississauga (ON): GlaxoSmithKline Inc., 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
- COVID-19: List of authorized drugs, vaccines and expanded indications
- 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

Health Product InfoWatch Editorial Team
Marketed Health Products Directorate
Health Canada
Address Locator 1906C
Ottawa ON K1A 0K9
Telephone: 613-954-6522
Teletypewriter: 1-800-465-7735 (Service Canada)

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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.

ISSN: 2368-8025

Cat.: H167-1E-PDF

Pub.: 210715