Health Canada Santé Canada

Canada

Health Product
InfoWatch

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REPORTING ADVERSE REACTIONS

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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.

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. This page is updated weekly.

DRUG AND VACCINE AUTHORIZATIONS AND COMMUNICATIONS FOR COVID-19

Recent communications related to authorized COVID-19 vaccines and treatments are highlighted in this section.

Comirnaty (Pfizer-BioNTech COVID-19 Vaccine)

Comirnaty is now authorized as 2 different formulations and presentations: vials intended for use in children 5 to less than 12 years of age have an orange cap, and the vial labels also have an orange border. Vials intended for use in individuals 12 years of age and older have a purple cap. Each formulation has specific age authorizations, storage, handling, and preparation requirements. To provide timely access to Comirnaty for Canadians, Pfizer and BioNTech will continue to provide product vials and cartons of Pfizer-BioNTech COVID-19 Vaccine labelled in English-only for now.

Health Canada has authorized the use of Comirnaty as a booster shot. The booster is authorized for adults 18 years of age and older, to be used at least 6 months after an individual has completed their primary vaccine series. The Comirnaty COVID-19 booster is a full dose of the regular vaccine (30 mcg).

Health Professional Risk Communication (November 19, 2021) – Comirnaty (authorization 5 to less than 12 years of age)
Statement (November 19, 2021) – Comirnaty (authorization 5 to less than 12 years of age)
Statement (November 9, 2021) – Comirnaty (booster)

Janssen COVID-19 Vaccine

As an extraordinary measure to provide immediate access to vaccine supplies in the context of the global pandemic, Janssen Inc. is providing vaccine vials and cartons labelled with European Union English-only labels. These labels are presented in English-only and are missing some important Canadian-specific information normally found on Health Canada approved labels.

Health Professional Risk Communication – Janssen COVID-19 Vaccine

Janssen and Vaxzevria (AstraZeneca) COVID-19 vaccines

Health Canada informed Canadians and healthcare professionals about changes to the product labels of the Janssen and Vaxzevria (AstraZeneca) COVID-19 vaccines. The label of the Janssen COVID-19 Vaccine has been updated to provide additional information about the very rare risk of immune thrombocytopenia (ITP) and the rare risk of venous thromboembolism following vaccination. The label of the Vaxzevria (AstraZeneca) COVID-19 vaccine has been updated to provide additional information about the very rare risk of thrombocytopenia, including the very rare risk of ITP, following vaccination.

Advisory – Janssen and Vaxzevria (AstraZeneca) COVID-19 vaccines

Sotrovimab

Sotrovimab for injection was authorized for use in Canada on July 30, 2021, in accordance with the Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19. Sotrovimab is indicated for the treatment of mild to moderate COVID-19, confirmed by direct SARS-CoV-2 viral testing, in adults and adolescents (12 years of age and older weighing at least 40 kg) who are at high risk for progressing to hospitalization and/or death. At this time, GlaxoSmithKline is providing sotrovimab with European French and English labelling, in order to expedite the distribution of the product.

Health Professional Risk Communication – Sotrovimab

Spikevax (COVID-19 Vaccine Moderna)

Health Canada has authorized a 2-month shelf life extension (from 7 months to 9 months) for certain lots of Spikevax (previously COVID-19 Vaccine Moderna). This extension applies to lots of US-labelled vaccine supplies with English-only vial and carton labels. The lots with extended expiry dates are identified in the "Products Affected" table in the risk communication.

At this time, Moderna is also providing vaccine supplies with vials and cartons labelled with the brand name Spikevax. This label is presented in English-only and is missing some important Canadian-specific information normally found on Health Canada approved labels.

Health Canada has authorized the use of Spikevax as a booster shot. The booster is authorized for adults 18 years of age and older, to be used at least 6 months after an individual has completed their primary vaccine series. The Spikevax COVID-19 booster is a half dose of the regular vaccine (50 mcg).

Statement (November 12, 2021) – Spikevax (booster)
Health Professional Risk Communication (November 10, 2021) – Spikevax (English-only labelling)
Health Professional Risk Communication (October 29, 2021) – Spikevax (shelf life)

Notice of Compliance for COVID-19 drugs and vaccines

On September 16, 2020, the Minister of Health signed the Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19 (Interim Order) to allow for the expedited authorization of COVID-19 drugs and vaccines. The Interim Order expired on September 16, 2021, and products authorized under the Interim Order can now be transitioned to the *Food and Drug Regulations* (FDR), after the market authorization holder submits a New Drug Submission to Health Canada for review. The FDR were amended to permit the same flexibilities provided by the Interim Order (e.g., rolling submissions, terms and conditions for monitoring and pre-positioning). Authorization under the FDR will provide the companies with some additional benefits, such as data protection. New COVID-19 products are eligible to apply directly to the FDR.

Vaxzevria and Janssen COVID-19 Vaccine, originally authorized under the Interim Order, have now been issued Notices of Compliance (NOC) under the FDR. These authorizations do not reflect any change in the safety or efficacy profile of these products or in how they are administered, but are a transition in the regulatory mechanism to allow continued access for Canadians to products that provide protection against and treatment for COVID-19.

Brand name	Date of NOC issuance	Brand name as authorized under the Interim Order	Date of Interim Order authorization
Vaxzevria	November 19, 2021	AstraZeneca COVID-19 Vaccine	February 26, 2021
Janssen COVID-19 Vaccine	November 23, 2021	Janssen COVID-19 Vaccine	March 5, 2021

Canadian product monographs for authorized vaccines and treatments for COVID-19 can be accessed through the COVID-19 vaccines and treatments portal or Health Canada's Drug Product Database.

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 October 2021 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*.*

Advil Cold & Sinus Day/Night Convenience Pack Advisory	GlaxoSmithKline Consumer Healthcare ULC recalled 2 lots of Advil Cold & Sinus Day/Night Convenience Pack due to a labelling error on the blister pack. The foil backing on the blister pack is rotated upside down and misaligned, so the nighttime caplets are labelled as daytime caplets, and some daytime caplets are labelled as nighttime caplets.

Certain hand sanitizers that may pose health risks Advisory	Health Canada advised Canadians that certain hand sanitizers were recalled because they either contained ingredients that were not permitted by Health Canada, were not properly labelled, were unauthorized, or were missing important safety information.
GENIUS Kids and Teens softgel capsules Advisory	Nutripur Inc. recalled 1 lot of GENIUS Kids and Teens softgel capsules due to possible bacterial contamination with Staphylococcus aureus. Nutripur Inc. has advised that only 17 bottles from the affected lot were sold to individuals (the remaining affected products have been recalled from distribution at the retail and wholesale level): 11 bottles at Marché Avril (QC), 1 bottle at Coop La Manne (QC), and 5 bottles at Oliver Health Food (AB).
Ivermectin Advisory	Health Canada reminded Canadians not to use ivermectin to prevent or treat COVID-19. Canadian poison centres have seen an increase in reports concerning ivermectin over the summer.
Losartan Advisory	Several companies recalled multiple lots of prescription losartan tablets, in 25 mg, 50 mg and/or 100 mg strengths, after tests found an azido impurity above the acceptable limit. Refer to the Affected Products table in the advisory for information on the recalled lots.
Novo-Gesic Forte/Acetaminophen Advisory	Teva Canada recalled 2 lots of Novo-Gesic Forte/Acetaminophen tablets, sold in 500 mg tablets, due to a labelling error that could result in a person exceeding the maximum daily dosage for acetaminophen.
Ombrelle Garnier Complete Dry Mist Spray sunscreen Advisory	Ombrelle Canada recalled all lots of Ombrelle Garnier Complete Dry Mist Spray sunscreen, SPF 30 and SPF 60, due to elevated levels of benzene.
Riva-Risperidone Advisory	Laboratoire Riva Inc. recalled 1 lot of Riva-Risperidone 0.25 mg tablets due to a packaging error. Some bottles may incorrectly contain only Riva-Gabapentin 100 mg capsules. Pharmacists may not recognize the error and may inadvertently repackage and dispense pill bottles that contain the wrong medication.

Tinactin Advisory	Bayer Inc. recalled 6 lots of Tinactin products (Tinactin Aerosol Powder, Tinactin Chill Deodorant Powder Spray, and Tinactin Chill Liquid Spray) due to potentially elevated levels of benzene.
Unauthorized health products Advisory – Unauthorized injectable drugs and medical devices seized from Vivian Spa in Mississauga, ON Advisory – Various unauthorized health 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 similar 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.

Mavenclad (cladribine)

The *Warnings and Precautions*, *Dosage and Administration* and *Patient Medication Information* sections of the Canadian product monograph for Mavenclad have been updated to include information about the **risk of liver injury** and monitoring requirements for this risk.

Key messages for healthcare professionals:[1]

- Liver injury, including serious cases, has been reported uncommonly during post-marketing experience in patients treated with Mavenclad. Cases involved mainly patients with a history of abnormal liver tests, a history of liver injury associated with other medications, or concomitant or recent treatment with medications known to cause liver injury. Liver injury has occurred from days to several months after initiating treatment with Mavenclad, but in the majority of serious cases the time to onset was within the first 4 weeks of the most recent dose of Mavenclad. Caution is recommended when considering treatment with Mavenclad in patients who may be susceptible to liver injury such as patients with a history of abnormal liver tests, history of liver injury during treatment with other drugs, including other disease modifying therapies used for

treatment of multiple sclerosis, or patients treated concomitantly or recently with medications known to cause liver injury.

- For all patients, obtain serum aminotransferase, alkaline phosphatase, and total bilirubin levels prior to initiation of therapy in year 1 and year 2. Monitoring of liver enzymes and total bilirubin levels should also be considered prior to administering week 2 doses, especially for patients who may be more susceptible to developing liver injury. Treatment should be delayed in patients with clinically significant serum aminotransferase, alkaline phosphatase, or total bilirubin abnormalities.

- Patients should be advised to immediately report any signs or symptoms of hepatotoxicity (e.g., unexplained nausea, vomiting, abdominal pain, fatigue, anorexia, or jaundice and/or dark urine). If a patient develops clinical signs, including unexplained liver enzyme elevations or symptoms suggestive of hepatic dysfunction, promptly measure serum transaminases and total bilirubin and interrupt or discontinue treatment with Mavenclad, as appropriate.

Reference

1. *Mavenclad (cladribine oral tablets)* [Product Monograph]. Mississauga (ON): EMD Serono, a Division of EMD Inc., Canada; 2021.

Synthroid (levothyroxine sodium)

Due to a change in the benefit-risk profile, the following indication for Synthroid has been **removed** throughout the Canadian product monograph: the treatment or prevention of various types of euthyroid goiters, including thyroid nodules and multinodular goiter.

Key messages for healthcare professionals:[1]

- The updated indications for Synthroid include:
  - **Hypothyroidism:** Synthroid is indicated as a replacement or supplemental therapy in patients of any age with primary (thyroidal), secondary (pituitary), and tertiary (hypothalamic) hypothyroidism of any etiology, in any state (including pregnancy) except transient hypothyroidism during the recovery phase of subacute thyroiditis;
  - **Pituitary Thyrotropin (Thyroid-stimulating hormone, TSH) Suppression:** Synthroid is indicated as an adjunct to surgery and radioactive iodine therapy in the management of thyrotropin-dependent well-differentiated papillary or follicular carcinoma of the thyroid.

Reference

1. *Synthroid (levothyroxine sodium)* [product monograph]. Etobicoke (ON): BGP Pharma ULC.; 2021.

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
- 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

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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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