Health Canada Santé Canada

Canada

Health Product InfoWatch

October 2022

CONTENTS

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

Pharmaceuticals and biologics

- Actemra (tocilizumab)
- Bamlanivimab (bamlanivimab)
- Casirivimab and imdevimab (casirivimab / imdevimab)
- Comirnaty (Pfizer-BioNTech COVID-19 Vaccine)
- Comirnaty Original & Omicron BA.4/BA.5 Bivalent Vaccine
- Evusheld (cilgavimab / tixagevimab)
- Janus Kinase (JAK) Inhibitors
- Paxlovid (nirmatrelvir and ritonavir)
- Sotrovimab (sotrovimab)
- Spikevax (COVID-19 Vaccine Moderna)
- Veklury (remdesivir)
- Zolgensma (onasemnogene abeparvovec)

Medical Devices

- Philips Respironics sleep therapy masks

Natural and non-prescription health products

- Hand sanitizers that may pose health risks

Other

- Unauthorized health products

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.

Actemra (tocilizumab)

On October 13, 2022, Health Canada authorized Actemra for the treatment of hospitalized adult patients with COVID-19 who are receiving systemic corticosteroids, and require supplemental oxygen, non-invasive or invasive mechanical ventilation or extracorporeal membrane oxygenation.

Authorization with terms and conditions

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

On October 7, 2022, Health Canada authorized the bivalent vaccine, Comirnaty Original & Omicron BA.4/BA.5, as a booster dose for active immunization against COVID-19 in individuals 12 years of age and older.

Comirnaty Original & Omicron BA.4/BA.5 bivalent vaccine (DIN 02531461), which does NOT require dilution, has the same GRAY CAP and GRAY LABEL BORDER as monovalent Comirnaty (COVID-19 Vaccine, mRNA) 30 mcg/0.3 mL – Do NOT dilute (DIN 02527863).

In order to provide rapid access to Comirnaty Original & Omicron BA.4/BA.5 bivalent vaccine, 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. However, this information is available on the federal government’s covid-vaccine.canada.ca website.

Health Product Risk Communication
Authorization with terms and conditions

Evusheld (tixagevimab and cilgavimab for injection)

On October 18, 2022, Health Canada authorized Evusheld for the treatment of mild to moderate COVID-19 in adults and adolescents (> 12 years of age weighing at least 40 kg). Evusheld may not be effective against certain SARS-CoV-2 Omicron subvariants when used as a prophylaxis or treatment for COVID-19. Decisions regarding the use of Evusheld should take into consideration what is known about the characteristics of the circulating SARS-CoV-2 viral variants, including geographical prevalence and individual exposure to variants.

Health Product Risk Communication

Review article

Omicron variant and COVID-19 treatments - Update

Health Canada is providing an update on the effectiveness of authorized treatments against the COVID-19 variants of concern that are currently circulating. In February 2022, Health Canada published information on COVID-19 treatment effectiveness against the Omicron BA.1 subvariant.[1]

Based on recent epidemiology data* collected by the Public Health Agency of Canada, provincial and territorial partners, and the Canadian COVID-19 Genomics Network, the Omicron BA.4 and BA.5 subvariants currently account for the majority of new COVID-19 cases reported in Canada.[2]

The major changes observed in the Omicron variant are predominantly within the sequence of the spike protein. Health Canada has requested that manufacturers of authorized COVID-19 treatments provide data on the effectiveness of their respective products against the Omicron variant (see Table 1).

Table 1: List of authorized treatments for COVID-19 in Canada*

Product name	Type of product	Date of Authorization
Veklury (remdesivir)	Antiviral	2020-07-27
Bamlanivimab (bamlanivimab)	Monoclonal Antibody	2020-11-20
Casirivimab and imdevimab (casirivimab / imdevimab)	Monoclonal Antibody	2021-06-09
Sotrovimab (sotrovimab)	Monoclonal Antibody	2021-07-30
Paxlovid (nirmatrelvir and ritonavir)	Antiviral	2022-01-17
Actemra (tocilizumab)	Immunosuppressant	2022-10-13
Evusheld (cilgavimab / tixagevimab)	Monoclonal Antibody	2022-10-18†

Monoclonal antibody therapies

Data from *in vitro* pseudovirus neutralization assays demonstrated the complete loss of neutralization potency against the Omicron BA.4/BA.5 subvariants for the casirivimab and imdevimab combination, and for bamlanivimab. The neutralization potency of sotrovimab has also been significantly reduced. As such, these treatments are highly unlikely to be effective against the Omicron BA.4/BA.5 subvariants.

Data from *in vitro* pseudovirus neutralization assays indicated that Evusheld retained some neutralization potency against most Omicron BA.4/BA.5 subvariants, but may have substantially reduced neutralization potency against the BA.4.6 subvariant. Health Canada has informed healthcare professionals about the risk of prophylaxis or treatment failure with Evusheld due to antiviral resistance.

Antiviral therapies

Based on available information, Veklury and Paxlovid are expected to maintain effectiveness against the Omicron variants, including the Omicron BA.4/BA.5 subvariants that are currently circulating.

Immunosuppressive therapies

Actemra is expected to maintain effectiveness against all COVID-19 variants, including the Omicron subvariants that are currently circulating.

The Canadian product monographs for COVID-19 treatments are continuously updated to include information about effectiveness against variants of concern as it becomes available.[3] The information in the Canadian product monographs for COVID-19 treatments, in conjunction with literature and local guidelines, should be consulted regularly for details regarding specific variants and antiviral resistance.

Health Canada will continue to closely monitor the effectiveness of authorized treatments against COVID-19 variants of concern.

References

1. Health Product InfoWatch: February 2022. Omicron Variant and COVID-19 Treatments. Ottawa (ON): Health Canada; 2022. (accessed 2022 Oct 11).
2. COVID-19 epidemiology update. COVID-19 variants in Canada. Ottawa (ON): Public Health Agency of Canada; 2022. (accessed 2022 Oct 11).
3. Drug Product Database. Ottawa (ON): Health Canada. Updated June 18, 2015. (accessed 2022 Oct 11).

Safety brief

The Use of mRNA COVID-19 vaccines (Comirnaty and Spikevax) during pregnancy and breastfeeding

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

COVID-19 infection during pregnancy is associated with an increased risk of severe illness and a higher risk for adverse pregnancy outcomes, such as preterm birth and/or stillborn infant.[3]

Health Canada reviewed the risk of pregnancy complications and the effects on breastfeeding individuals and breastfed newborns/infants following maternal vaccination with Comirnaty or Spikevax. The scope of the review included only monovalent mRNA vaccines (Comirnaty and Spikevax), as bivalent vaccines (Comirnaty Original & Omicron BA.4/BA.5 and Spikevax Bivalent) were not yet authorized at the time of the review. This safety assessment was triggered by the European Medicines Agency recommendation to update the product labelling to reflect accumulating evidence that COVID-19 mRNA vaccines can be used during pregnancy.[4,5]

Health Canada's review of the available information found no evidence that vaccination with Comirnaty or Spikevax increases the risk of having a miscarriage, preterm birth or other pregnancy complications. In addition, no increased risk for adverse events in breastfeeding individuals and breastfed newborns/infants was observed following maternal vaccination with Comirnaty or Spikevax.

The current Canadian product safety information for Comirnaty and Spikevax remains accurate and accounts for the evolving nature of the data. No updates to the Canadian product monographs for Comirnaty and Spikevax about their use in pregnancy and breastfeeding are planned at this time.

Healthcare professionals 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 their use during pregnancy and breastfeeding and will take appropriate action should new health risks be identified.

References

1. *Comirnaty (COVID-19 Vaccine, mRNA)* [product monograph]. Kirkland (PQ): Pfizer Canada ULC; 2022.
2. *Spikevax (Elasomeran mRNA vaccine)* [product monograph]. Cambridge (MA): ModernaTX, Inc; 2022.
3. COVID-19 during Pregnancy. Centers for Disease Control and Prevention; 2022 July 1 (accessed 2022 October 13).
4. COVID-19 vaccines safety update. Amsterdam (Netherlands): European Medicines Agency; 2022 February 17. (accessed 2022 October 3).
5. COVID-19: latest safety data provide reassurance about use of mRNA vaccines during pregnancy. Amsterdam (Netherlands): European Medicines Agency; 2022 January 18. (accessed 2022 October 3).

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 September 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.

Hand sanitizers that may pose health risks Advisory	Health Canada advised Canadians that certain hand sanitizers were recalled due to various safety-related issues, including the presence of ingredients that were not permitted by Health Canada, improper labelling, unauthorized products, and missing safety information.

Janus Kinase (JAK) Inhibitors Summary Safety Review	This safety review evaluated the risk of major adverse cardiovascular events, thrombosis, malignancies and/or all-cause mortality with the use of the Janus Kinase (JAK) Inhibitors, Xeljanz/Xeljanz XR (tofacitinib), Olumiant (baricitinib) and Rinvoq (upadacitinib). Health Canada's review found that a drug class effect for these risks with the use of JAK inhibitors cannot be excluded at this time. Health Canada is working with the manufacturers to update and align these risks in the Canadian product monographs for JAK inhibitors.
Philips Respironics sleep therapy masks Advisory	Certain Philips Respironics sleep therapy masks used with Continuous Positive Airway Pressure or Bi-Level Positive Airway Pressure machines have magnets in their headgear clips or straps. Their magnetic field can potentially affect their function or displace some metallic medical devices or objects (e.g., pacemakers, metallic stents, metal in the eye) which may result in serious injury. Philips Respironics is updating the product warnings and instructions for use to help prevent injury to patients and those close to them, who may be vulnerable to magnetic fields.
Unauthorized health products Counterfeit Nuceiva injectable drug seized from New You Spa in Vaughan, Ontario Unauthorized products may pose serious health risks	Health Canada advised Canadians about various unauthorized health products being sold at retail locations across Canada or online that may pose serious health risks.
Zolgensma (onasemnogene abeparvovec) Health Product Risk Communication	Two cases of fatal acute liver failure associated with Zolgensma have recently been reported internationally. The deaths occurred 6-7 weeks post-Zolgensma infusion, following the initiation of corticosteroid taper. Hepatotoxicity is an identified risk in the current Canadian product monograph for Zolgensma. Patients with pre-existing liver impairment or hepatic viral infection may be at higher risk. Health Canada is working with the manufacturer to update the Canadian product monograph, including the Serious Warnings and Precautions Box, to include fatal cases of acute liver failure and revise the guidance for monitoring liver function.

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)

Copyright

© 2022 His Majesty the King in Right of Canada. This publication may be reproduced without permission provided the source is fully acknowledged. The use of this publication for advertising purposes is prohibited. Health Canada does not assume liability for the accuracy or authenticity of the information submitted in case reports.

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

[*] At the time of publication.
[†] Evusheld (cilgavimab / tixagevimab) was authorized in April 2022 for the pre-exposure prophylaxis of COVID-19.