Health Canada Santé Canada

Canada

Health Product InfoWatch

February 2022

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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

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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

Amitriptyline
Bamlanivimab (bamlanivimab)
Casirivimab and Imdevimab
Nuvaxovid (COVID-19 Vaccine)
Paxlovid (nirmatrelvir and ritonavir)
Sotrovimab (sotrovimab)
Veklury (remdesivir)
Xeljanz/Xeljanz XR (tofacitinib)

Medical devices

Airvo 2 Humidifier
Esophageal stents

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, which is updated weekly.

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.

Review article

Omicron Variant and COVID-19 Treatments

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 (SARS-CoV-2 B.1.1.529 / BA.1) variant currently accounts for the majority of new COVID-19 cases reported in Canada.[1]

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 (see Table 1) provide data on the effectiveness of their respective products against the Omicron variant.

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

* At the time of publication.

Data from *in vitro* pseudovirus neutralization assays demonstrated the complete loss of neutralization potency against the Omicron variant for the casirivimab and imdevimab combination, and for bamlanivimab. As such, these treatments are highly unlikely to be effective against the Omicron variant. Health Canada has informed healthcare professionals about the high risk of treatment failure with casirivimab and imdevimab against the Omicron variant.

Data from *in vitro* pseudovirus neutralization assays indicated that sotrovimab retained its neutralization potency against the Omicron variant. As such, sotrovimab is expected to be effective against the Omicron variant.

The antiviral therapies, Paxlovid and Veklury, are expected to maintain effectiveness against the Omicron variant based on their mechanism of action.

The Canadian product monographs for COVID-19 treatments have been or will be updated to include information about efficacy with variants of concern as information becomes available.

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

Reference

1. *COVID-19 daily epidemiology update*. Ottawa (ON): Public Health Agency of Canada; 2022. (accessed 2022 Feb 2).

Nuvaxovid (COVID-19 Vaccine)

Nuvaxovid was authorized by Health Canada on February 17, 2022 for the active immunization to prevent coronavirus disease 2019 (COVID-19) caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 years of age and older.

Authorization with terms and conditions: Nuvaxovid (COVID-19 Vaccine)

ANNOUNCEMENT

How to report an adverse reaction to cannabis

In Canada, products containing cannabis fall into one of 3 categories:

1) cannabis for non-medical purposes, with no health claims or pre-market review for safety and efficacy; and

2) cannabis for medical purposes, obtained via authorization from a healthcare practitioner, with no health claims or premarket review for safety and efficacy, both of which are regulated under the *Cannabis Act* and its Regulations; and

3) health products containing cannabis (or for use with cannabis), such as prescription drugs and medical devices, that are marketed with health claims and subject to premarket authorization by

Health Canada under the *Food and Drugs Act* and its Regulations.[1] These products are also subject to certain requirements under the *Cannabis Act*.

Health Canada's ability to monitor health and safety issues with cannabis depends on healthcare professionals, consumers and licence holders reporting adverse reactions. Healthcare professionals and consumers are encouraged to report any adverse reactions associated with cannabis, regardless of its use, to Health Canada. Under the *Cannabis Regulations*, licence holders who sell or distribute a cannabis product must report all serious adverse reactions to Health Canada.

Adverse reaction reporting for cannabis products

To assist Health Canada in conducting thorough assessments of adverse reactions, reports should include as much of the following information as possible:

- product information (brand name, licence holder, amount of THC and/or CBD and other ingredients such as other cannabinoids, terpenes or carrier oils; lot or batch number); place and date of purchase
- details of use, including the amount used, frequency and duration of product use (including start and stop date(s)) and route(s) of administration
- other suspect products (if any)
- concomitant health products or other substances
- patient's medical history, including whether the patient was cannabis naïve or not, whether they previously consumed the suspected cannabis product and any previous known hypersensitivities or allergies to cannabis or other substances/health products
- description of the adverse reaction, including date of onset and duration
- seriousness of the adverse reaction and reason for seriousness
- any dechallenge/rechallenge information
- outcome

Adverse reactions to cannabis should be reported to Health Canada even if certain information is unknown or missing, particularly those involving vulnerable populations, including children or the elderly, or adverse reactions of interest, including suspected vaping-associated lung illness or cannabis-drug interactions, regardless of how the cannabis was obtained.

For inquiries related to this communication or information on adverse reaction reporting for cannabis, contact the Controlled Substances and Cannabis Branch at cannabis@canada.ca

Helpful links on cannabis

Information for healthcare professionals: Cannabis (marihuana, marijuana) and the cannabinoids

Information on cannabis adverse reaction reporting: Cannabis adverse reaction reporting guide

Legal cannabis retailers: Authorized cannabis retailers in the provinces and territories

Licence holders: Licensed cultivators, processors and sellers of cannabis

Reference

1. *Health products containing cannabis or for use with cannabis: Guidance for the Cannabis Act, the Food and Drugs Act, and related regulations*. Ottawa (ON): Health Canada; 2018 July. (accessed 2022 Feb. 15)

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 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.

Airvo 2 Humidifier Summary Safety Review	This safety review evaluated the risk of breathing problems associated with the Airvo 2 Humidifier when there is an undetected, accidental disconnection of the nasal cannula from patients. Health Canada's review of the available information concluded that the design of the Airvo 2 Humidifier is appropriate for its use, and its instructions for use are clear. It is not intended for life support, and patient monitoring should be performed at all times. Health Canada will continue to monitor the safety of the Airvo 2 Humidifier.
Amitriptyline Advisory	AA Pharma Inc. recalled 2 lots of Elavil (amitriptyline) and Apotex Inc. recalled 1 additional lot of APO-Amitriptyline 10 mg tablets due to the presence of N-nitrosodimethylamine (NDMA), a nitrosamine impurity, above the acceptable limit.
Esophageal stents Summary Safety Review	This safety review evaluated the risk of bilateral vocal cord paralysis associated with esophageal stents. Health Canada's review of the available information did not establish a link. Health Canada will continue to monitor safety information involving esophageal stents.
Unauthorized health products Advisory	Health Canada advised Canadians about various unauthorized health products being sold at retail locations across Canada or online that may pose serious health risks.
Xeljanz/Xeljanz XR (tofacitinib) Summary Safety Review	This safety review evaluated the risks of major adverse cardiovascular events and malignancies associated with the use of Xeljanz/Xeljanz XR. Health Canada's review of the available information found a link. Health Canada has worked

Health Professional Risk Communication Advisory	with the manufacturer to update the Canadian product monograph to highlight these risks, including a warning statement about the use of Xeljanz/Xeljanz XR in specific populations. Health Canada has also communicated about these and other risks related to Xeljanz/Xeljanz XR to healthcare professionals and Canadians.

HEALTH CANADA NEWS

New interface for the Canada Vigilance adverse reaction online database: Seeking healthcare professional volunteers for user testing

Health Canada is developing a new interface for the Canada Vigilance adverse reaction online database. The new interface is an interactive, web-based tool (termed a "dashboard"), that is intended to make the data easier to search and displays results in a more user-friendly format. Health Canada is currently recruiting volunteer healthcare professionals to perform user testing of this new dashboard. Interested parties should send an email to: CVInterfaceFeedback.CommentairesInterfaceCV@hc-sc.gc.ca.

Did You Know?

The Canada Vigilance adverse reaction online database contains information about suspected adverse reactions to health products. Adverse reaction reports are submitted by consumers, healthcare professionals, market authorization holders and hospitals. Health Canada uses the information in the Canada Vigilance database to monitor the safety of health products after they have received market authorization.

Scope

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Reporting Adverse Reactions

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For more information on how to report an adverse reaction, visit the Adverse Reaction and Medical Device Problem Reporting page.

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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