



Health Product InfoWatch

May 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

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

Accupril (quinapril hydrochloride)
Apo-Acyclovir (acyclovir)
Comirnaty (Pfizer-BioNTech COVID-19 Vaccine)
Janssen COVID-19 Vaccine
Veklury (remdesivir)

Medical devices

Breast implants

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.

Comirnaty (Pfizer-BioNTech COVID-19 Vaccine)

On March 15, 2022, a new formulation/presentation of Comirnaty (COVID-19 Vaccine, mRNA), 30 mcg/0.3 mL for use in individuals 12 years of age and older, was authorized by Health Canada. This new formulation/presentation, which has a GRAY vial cap and GRAY label border, does NOT require dilution and has different storage requirements. Comirnaty is now authorized as 3 different formulations/presentations, which are clearly differentiated by their vial cap and label border colours.

In addition, to expedite the distribution of vaccine supplies in the context of the pandemic, Pfizer and BioNTech are continuing to provide vaccine supplies with vials and cartons labelled with the name Pfizer-BioNTech COVID-19 Vaccine. Health Canada is permitting the use of an English-only label for a limited period. Health Canada has imposed terms and conditions requiring Pfizer Canada ULC to provide vaccine supplies with Canadian-specific labels as soon as feasible. Health Canada has made full labelling information available in French and English on the federal government's covid-vaccine.canada.ca website.

[Health Product Risk Communication](#)

Janssen COVID-19 Vaccine

Health Canada has authorized the use of Janssen COVID-19 Vaccine as a booster shot. A booster dose of 0.5 mL of Janssen COVID-19 Vaccine may be administered intramuscularly at least 2 months after the primary vaccination in individuals 18 years of age and older.

[COVID-19 vaccines and treatments portal](#)

Veklury (remdesivir)

The indication for Veklury (remdesivir) has been expanded to include non-hospital use. Veklury is now indicated for the treatment of coronavirus disease 2019 (COVID-19) in:

- Hospitalized adults and adolescents (aged 12 to less than 18 years who weigh at least 40 kg) with pneumonia requiring supplemental oxygen;
- Non-hospitalized adults with positive results of direct severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death.

[COVID-19 vaccines and treatments portal](#)

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 April 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](#).

Accupril (quinapril hydrochloride) Advisory	Pfizer Canada ULC recalled all lots of Accupril (quinapril hydrochloride) in 10 mg, 20 mg and 40 mg strengths due to the presence of a nitrosamine impurity (<i>N</i> -nitroso-quinapril) above the acceptable level.
Apo-Acyclovir (acyclovir) Advisory	Apotex Inc. recalled certain lots of Apo-Acyclovir (acyclovir) tablets, in 200 mg and 800 mg strengths, due to the presence of a nitrosamine impurity (<i>N</i> -nitrosodimethylamine [NDMA]) above the acceptable level.
Breast implants Summary Safety Review Advisory	Health Canada has updated its 2019 and 2017 safety reviews on breast implant-associated anaplastic large cell lymphoma (BIA-ALCL). The review found that there continues to be an increased risk of BIA-ALCL with the use of highly textured (macro-textured) implants in comparison with those having less textured (micro-textured) or smooth implants. Health Canada has worked with manufacturers to strengthen the labelling of all breast implants with information regarding the risk of BIA-ALCL by including box warnings of this risk. Health Canada has also communicated this information to Canadians.

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.

Unauthorized health products

Advisory: Various unauthorized products

Advisory: Unauthorized health products seized from three herbal medicine stores in Calgary, Alberta

Health Canada advised Canadians about various unauthorized health products being sold at retail locations across Canada or online that may pose serious health risks.

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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