Health Canada Santé Canada

Canada

Health Product InfoWatch

April 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

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Accuretic (quinapril hydrochloride and hydrochlorothiazide)
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Diphenhydramine-containing products
Ranitidine

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.

Evusheld (tixagevimab and cilgavimab for injection)

Evusheld (tixagevimab and cilgavimab for injection) was authorized by Health Canada on April 14, 2022. Evusheld is indicated for the pre-exposure prophylaxis of coronavirus disease 2019 (COVID-19) in adults and adolescents (≥12 years of age weighing at least 40 kg), who have not had a known recent exposure to an individual infected with SARS-CoV-2 and:

- Who are immune compromised and unlikely to mount an adequate immune response to COVID-19 vaccination or
- For whom COVID-19 vaccination is not recommended.

In order to provide rapid access to Evusheld, AstraZeneca will distribute product vials and cartons with global labels in English only for a limited period of time.

Authorization with terms and conditions
Health Professional Risk Communication

Sotrovimab for injection

Sotrovimab, 500 mg IV, is unlikely to maintain efficacy against the Omicron BA.2 subvariant. Current data indicates that sotrovimab continues to be effective against the Omicron BA.1 and BA.1.1 subvariants.

Health Professional Risk Communication

ANNOUNCEMENTS

Updated Recalls and Safety Alerts System

An updated Recalls and Safety Alerts system is now live, providing Canadians with easy access to a comprehensive list of recalls, advisories and safety alerts from Health Canada and other Government partners.

Health product safety information that can be found at this website includes Health Product Risk Communications, Public Advisories, and Recall Notices.

The new website is mobile-friendly with improved content navigation and better search features, allowing for filtering by product category and issue, including a filter for COVID-19 safety information. Updates also include an email notification and subscription service to alert to new postings.

Transition of tramadol to a controlled substance and narcotic

On March 31, 2022, tramadol was removed from the Canadian Prescription Drug List, and added to Schedule I of the Controlled Drugs and Substances Act and the Narcotic Control Regulations. Tramadol products currently sold and distributed by manufacturers must include the updated labelling with the "N" narcotic symbol. In order to facilitate this transition and avoid disruption in market access, any products already sold and distributed by manufacturers prior to March 31, 2022, or product remaining at wholesalers or pharmacies, may continue to be sold until market depletion.

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 March 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 Health Product Risk Communication	Intravenous bags of Baxter's 0.9% Sodium Chloride Injection, USP 500 mL and Lactated Ringer's Injection, USP 500 mL from certain lots have the potential to leak when administered under pressure infusion due to a weak seal formation. Affected lots were **not** recalled to prevent a shortage of these medically necessary products.

Accupril (quinapril hydrochloride) and Accuretic (quinapril hydrochloride and hydrochlorothiazide) Advisory	Pfizer Canada ULC recalled all lots of Accupril (quinapril hydrochloride) in 10 mg, 20 mg and 40 mg strengths and all lots of Accuretic (quinapril hydrochloride and hydrochlorothiazide) medication in 10/12.5 mg, 20/12.5 mg and 20/25 mg strengths due to the presence of a nitrosamine impurity (N-nitroso-quinapril) above the acceptable level.
Diphenhydramine-containing products Summary Safety Review Health Product InfoWatch	This safety review evaluated the risk of known and potential serious adverse events associated with the use of oral, over-the-counter diphenhydramine-containing products, at both recommended and higher doses, in children and adolescents. Health Canada's review of the available information found no change in the type or frequency of serious adverse events associated with the use of diphenhydramine-containing products to warrant regulatory action at this time. Health Canada has communicated this information to healthcare professionals and will continue to monitor safety information involving these products.
Inderal-LA (propranolol hydrochloride) Advisory	Pfizer Canada ULC recalled all lots of Inderal-LA (propranolol hydrochloride) extended release capsules, in 60 mg, 80 mg, 120 mg and 160 mg strengths, due to the presence of a nitrosamine impurity (N-nitroso-propranolol) above the acceptable level.
Ranitidine Advisory	Pharmascience Inc. recalled 30 lots of over-the-counter ranitidine drugs (150 mg tablets), packaged in blister packs, after tests found N-nitrosodimethylamine (NDMA), a nitrosamine impurity, above the acceptable level in some lots. The products are sold under various private labels.
Ruzurgi (amifampridine) Health Product Risk Communication	On March 10, 2022, for the second time, the Federal Court set aside Health Canada’s decision to authorize Ruzurgi (amifampridine), and the second Notice of Compliance that had been issued on June 24, 2021 is considered invalid. Therefore, Ruzurgi is no longer authorized for sale in Canada. Healthcare professionals should proactively contact their patients taking Ruzurgi to discuss alternatives. Access to Ruzurgi can be requested under the Special Access Program, where marketed alternatives are not clinically appropriate.
Sodium Acetate Injection, USP Health Product Risk Communication	Fresenius Kabi Canada Ltd. has identified visible particulate matter in certain vials of Sodium Acetate Injection, USP from lot 6126554 during routine retention sample testing. The distributed vials from the affected lot were **not** recalled due to shortages of this product.

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.

NEW HEALTH PRODUCT SAFETY INFORMATION

The following topic has been selected to raise awareness and encourage reporting of similar adverse reactions.

Product monograph update

The following safety labelling update, which was recently made to the Canadian product monograph, has 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.

Agrylin (anagrelide hydrochloride)

The *Warnings and Precautions, Dosage and Administration,* and *Patient Medication Information* sections of the Canadian product monograph for Agrylin have been updated with the risk of **thrombotic complications** upon abrupt treatment discontinuation or substantial dose reduction.

Key messages for healthcare professionals:[1]

- Thrombotic complications have been reported in patients following sudden treatment withdrawal, dose interruption (including medical procedures), and in patients at maintenance doses but in which platelet counts were above 600,000/µL.
- Abrupt treatment discontinuation or substantial reduction of anagrelide's dose should be avoided due to the risk of sudden increase in platelet counts, which may lead to potentially fatal thrombotic complications, such as cerebral infarction.
- In the event that multiple doses are missed during long-term treatment, the patient should contact their healthcare professional immediately and platelets should be monitored.

Reference

1. *Agrylin (anagrelide hydrochloride)* [product monograph]. Toronto (ON): Takeda Canada 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
- 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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