Health Canada Santé Canada

Canada

Health Product InfoWatch

June 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

- Casirivimab and Imdevimab
- Comirnaty (Pfizer-BioNTech COVID-19 Vaccine)
- Gleevec (imatinib mesylate)
- Leucovorin Calcium Injection
- Omnipaque (iohexol injection USP)
- Sodium Acetate Injection, USP
- Spikevax (COVID-19 Vaccine Moderna)
- Tabrecta (capmatinib)
- Thiotepa for injection USP
- Valacyclovir-containing products
- Visipaque (iodixanol injection USP)

Medical devices

- Plasma pens

Natural and non-prescription health products

- Compliments Advanced Relief Eye Drops
- Pharmasave Advanced Relief Eye Drops

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.

Casirivimab and Imdevimab

The *Indications* and *Microbiology* sections of the Canadian product monograph for Casirivimab and Imdevimab have been updated with information about the high risk of treatment failure against the SARS-CoV-2 BA.1/BA.1.1 variants (Omicron) and the potential risk of treatment failure against the Omicron BA.2 variant. Health Canada has previously informed healthcare professionals about this risk.

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. Health Canada has also issued a new DIN (DIN 02527863) for this new formulation/presentation to minimize potential medication error between available presentations of Comirnaty in Canada.

On June 1, 2022, Health Canada authorized a single booster dose of Comirnaty for individuals 16 and 17 years of age, to be used at least 6 months following the primary 2-dose series.

Health Product Risk Communication
COVID-19 vaccines and treatments portal

Spikevax (COVID-19 Vaccine Moderna)

On June 1, 2022, Health Canada authorized a new presentation of Spikevax (elasomeran) with a concentration of 0.10 mg/mL in a 2.5 mL multidose vial with a ROYAL BLUE CAP. The volume (mL) required for primary series and booster dosing will be different depending on which presentation of the vaccine is being administered. Careful attention should be paid to the vial and carton label, vial cap colour and corresponding dose volumes. In order to provide rapid access to the new presentation of Spikevax (0.10 mg/mL, 2.5 mL multidose vial), Moderna will distribute the vaccine product with English-only vial and carton labels for a period of time. As a result, important Canadian-specific information is absent from these labels.

Health Product Risk Communication

ANNOUNCEMENTS

Shortage of iodinated contrast media

Health Canada is aware of a shortage of iodinated contrast media widely used in hospital and clinical settings for CT scans and X-ray imaging. GE Healthcare Canada Inc. is experiencing shortages of Omnipaque (iohexol injection USP) and Visipaque (iodixanol injection USP) iodinated contrast media due to a COVID-19 related factory shutdown in China. The shortage is presently affecting numerous countries. Although alternative agents are marketed in Canada, the available supplies are not adequate to make up for the shortage of Omnipaque and Visipaque. Health Canada is working with stakeholders, including GE Healthcare Canada Inc. and the Canadian Association of Radiologists, to coordinate information sharing and identify mitigation strategies. Stakeholders in the provincial/territorial healthcare systems are implementing conservation guidelines to preserve available supply.

For information about drug shortages and discontinuations in Canada, please visit the Drug Shortages Canada webpage.

Management and Prevention of Harmful Medication Incidents

Health Canada performs many regulatory activities to help protect the health and safety of Canadians. In addition to monitoring the safety profile of health products once they are marketed to ensure that the benefits of the products continue to outweigh the risks, Health Canada also has a role to play in reducing and preventing harmful medication incidents, particularly those that result from a health product's name, package or label.

A medication incident (also known as a medication error) is any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of a healthcare professional, patient or consumer.

Medication incident and adverse reaction reports are both important sources of information about the safety of a health product.

Adverse reactions should be reported to Health Canada's Canada Vigilance Program.

Medication incidents should be reported to the Canadian Medication Incident Reporting and Prevention System (CMIRPS) under the "How do I report" tab.

Health Canada uses the information gathered through CMIRPS as part of its ongoing activities to monitor and improve the safety of medications and other health products in Canada. The Department conducts analysis of medication incident reports to reduce and prevent the occurrence of medication incidents related to health product names, packages and labels. Health Canada also develops standards, guidelines, best practices and guidance for industry to support the safe use of health products through optimal health product naming, packaging and labelling.

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 May 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.

Leucovorin Calcium Injection Type 1 drug recall	Leucovorin Calcium Injection was recalled, as the assay is out of specification in the affected lot(s).
Pharmasave Advanced Relief Eye Drops and Compliments Advanced Relief Eye Drops Advisory	Teva Canada Ltd. recalled one lot each of Pharmasave Advanced Relief Eye Drops and Compliments Advanced Relief Eye Drops because of a packaging error. Some bottles may contain ingredients that are not listed on the label and that may pose health risks to individuals who are allergic to the ingredients.
Plasma pens Information Update	Health Canada has authorized the sale of certain plasma pens in Canada for use by healthcare professionals only.
Sodium Acetate Injection, USP Health Product Risk Communication	Further to the communication issued on March 15, 2022, regarding the potential for the presence of particulate matter in vials of Sodium Acetate Injection, USP (DIN 02139529) from lot 6126554, Fresenius Kabi Canada Ltd., in consultation with Health Canada, provided updated information on the filters to be used with distributed vials from this affected lot. Healthcare professionals are reminded to carefully inspect all sodium acetate injectable products, regardless of the lot, before and after dilution and all intravenous bags. If

	particulate matter is observed, the product should NOT be administered.
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.
Valacyclovir-containing products Summary Safety Review	This safety review evaluated the risk of drug reaction with eosinophilia and systemic symptoms (DRESS) with the use of valacyclovir-containing products. Health Canada's review of the available information concluded that there may be a link. Health Canada will work with the manufacturers to update the Canadian product monographs for valacyclovir-containing products to include the risk of DRESS.

NEW HEALTH PRODUCT SAFETY INFORMATION

The following topics have been selected to raise awareness and/or 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.

Gleevec (imatinib mesylate)

The *Post-Market Adverse Reactions* and *Patient Medication Information* sections of the Canadian product monograph for Gleevec have been updated with the risk of **thrombotic microangiopathy**.

Key message for healthcare professionals:[1]

- Thrombotic microangiopathy has been reported during post-marketing use of Gleevec.

Reference

1. *Gleevec (imatinib mesylate)* [product monograph]. Dorval (QC): Novartis Pharmaceuticals Canada Inc., 2022.

Notice of market authorization with conditions

A Notice of Compliance with Conditions (NOC/c) is a form of market authorization with conditions granted to a product on the basis of ***promising*** *evidence of clinical effectiveness following review of the submission by Health Canada. Communicating a NOC/c is intended to raise awareness on the details of the drug and the type of authorization granted.*

Healthcare professionals are encouraged to report to Health Canada any adverse reactions suspected of being associated with marketed health products, including drugs authorized under the NOC/c policy.

The content of these notices reflects current information at the time of publication. Conditions associated with the NOC/c will remain until they have been fulfilled and authorized by Health Canada. For the most up-to-date information, consult Health Canada's NOC database.

Tabrecta (capmatinib): Authorization with conditions

Health Canada has issued a Notice of Compliance, under the NOC/c policy, for Tabrecta (capmatinib), tablets, 150 mg and 200 mg. Tabrecta is indicated for the treatment of adult patients with locally advanced unresectable or metastatic non-small cell lung cancer harbouring mesenchymal-epithelial transition exon 14 skipping alterations. Patients should be advised of the conditional market authorization for this indication.

For the complete prescribing information and information available for patients/caregivers, please consult the Tabrecta Canadian product monograph. The product monograph can be accessed through Health Canada's Drug Product Database, the Novartis Pharmaceuticals Canada Inc. website or by contacting Novartis Pharmaceuticals Canada Inc. at 1-800-363-8883. Contact the company for a copy of any references, attachments or enclosures.

Thiotepa for injection USP: Authorization with conditions

Health Canada has issued a Notice of Compliance, under the NOC/c policy, for Thiotepa for Injection USP, lyophilised powder for solution upon reconstitution and dilution, 15 mg / vial and 100 mg / vial, intravenous. Thiotepa for Injection USP is indicated, in combination with other chemotherapeutic products as part of a high-dose chemotherapy consolidation regimen followed by autologous stem cell transplantation, for adult patients with central nervous system lymphoma. Patients should be advised of the conditional market authorization for this indication.

For the complete prescribing information and information available for patients/caregivers, please consult the Thiotepa for Injection USP Canadian product monograph. The product monograph can be accessed through Health Canada's Drug Product Database, the SteriMax Inc. website or by contacting SteriMax Inc. at 1-800-881-3550. Contact the company for a copy of any references, attachments or enclosures.

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

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

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