Health Canada Santé Canada

Your health and safety… our priority. *Votre santé et votre sécurité… notre priorité.*

Health Product InfoWatch

July 2021

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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

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CORONAVIRUS DISEASE (COVID-19)

For the most up-to-date information on COVID-19, please visit the Government of Canada Coronavirus disease (COVID-19) website **Canada.ca/coronavirus**, which includes a dedicated section for healthcare professionals and for the health product industry.

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.

Canada

The COVID-19 vaccines and treatments portal provides information for consumers, healthcare professionals and researchers on vaccines and treatments authorized for COVID-19, as well as those currently under review.

For information about adverse events following immunization that individuals have reported after receiving a COVID-19 vaccine in Canada, please see visit the Reported side effects following COVID-19 vaccination in Canada webpage. This page is updated weekly.

DRUG AND VACCINE AUTHORIZATIONS AND COMMUNICATIONS FOR COVID-19

Recent communications related to authorized COVID-19 vaccines and treatments are highlighted in this section.

AstraZeneca COVID-19 Vaccine and COVISHIELD

Very rare cases of capillary leak syndrome (CLS) have been reported following vaccination with AstraZeneca COVID-19 Vaccine. A history of CLS was noted in some of the cases. A fatal outcome has been reported. AstraZeneca COVID-19 Vaccine and COVISHIELD are now contraindicated in individuals who have previously experienced episodes of CLS. Health Canada worked with the manufacturers of AstraZeneca COVID-19 Vaccine and COVISHIELD to update the product monographs for these products to include this new safety information, as well as other updates including additional guidance for healthcare professionals regarding thrombosis with thrombocytopenia syndrome.

Health Professional Risk Communication – AstraZeneca COVID-19 Vaccine and COVISHIELD

Advisory – AstraZeneca COVID-19 Vaccine and COVISHIELD

COVID-19 Vaccine Moderna

ModernaTx, Inc. is providing, at this time, US-labelled vaccine supplies in order to expedite the distribution of the vaccine in Canada. The US-labelled vaccine, named 'Moderna COVID-19 Vaccine', is supplied in a carton of 10 multiple-dose vials with 8 mL fill volume containing 14 doses (US label maximum 15 doses) of 0.5 mL each. This is different from the Health Canada authorized product that comes in vials containing 10 doses of 0.5 mL each. The vial and carton labels are presented in English-only and are missing some important Canadian-specific information normally found on Health Canada approved labels.

Health Professional Risk Communication – COVID-19 Vaccine Moderna

Pfizer-BioNTech and Moderna COVID-19 vaccines

Cases of myocarditis and/or pericarditis following immunization with COVID-19 vaccines have been reported in a small number of people in Canada and internationally. Health Canada worked with the manufacturers of the Pfizer-BioNTech and Moderna COVID-19 vaccines to update the product monographs to describe these very rare reports. Health Canada has also communicated this information to healthcare professionals.

Advisory – Pfizer-BioNTech and Moderna COVID-19 vaccines

Health Product InfoWatch – COVID-19 vaccines and reports of myocarditis and/or pericarditis

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 June 2021 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.

Certain hand sanitizers that may pose health risks Advisory	Health Canada advised Canadians that certain hand sanitizers were recalled because they either contained ingredients that were not permitted by Health Canada, were not properly labelled, were unauthorized, or were missing important information.
Champix (varenicline) Health Professional Risk Communication	Testing results received from Pfizer Canada ULC identified 5 lots of Champix (varenicline) with levels of a nitrosamine impurity, *N*-nitrosovarenicline, above the acceptable intake limit established by Health Canada. *N*-nitrosovarenicline has been shown to cause gene mutations in an *in vitro* study, indicating that its presence in Champix may be associated with a potential increased cancer risk in humans. As a result, Health Canada requested that Pfizer Canada ULC recall the 5 impacted lots. There is no immediate risk to patients taking this medication as an increased cancer risk would be associated with long-term use.

Dopamine agonists Summary Safety Review Health Product Infowatch	This safety review evaluated the risk of dopamine agonist withdrawal syndrome (DAWS) associated with the use of dopamine agonists (apomorphine-, bromocriptine-, cabergoline-, pergolide-, pramipexole-, quinagolide-, ropinirole-, rotigotine-containing products). Health Canada's review of the available information has established a link between the risk of DAWS and the use of pramipexole, quinagolide, or ropinirole, but could not establish a link with apomorphine, bromocriptine, cabergoline, pergolide, or rotigotine. Health Canada will work with manufacturers to update the relevant Canadian product monographs with language in line with the current level of evidence. Health Canada has also communicated this information to healthcare professionals.
Irbesartan, losartan and valsartan drugs Advisory	Several companies recalled multiple lots of irbesartan, losartan and valsartan drug products after tests found an azido impurity above the acceptable limit.
Kadcyla (trastuzumab emtansine) Summary Safety Review	This safety review evaluated the risk of tumor lysis syndrome associated with Kadcyla (trastuzumab emtansine). Health Canada's review of the available information could not confirm a link, as the information related to this risk in Canada is too limited. Health Canada has asked the manufacturer for additional information about the risk of tumor lysis syndrome related to the use of Kadcyla in Canada and in other jurisdictions, and will review this information to determine if any measures are needed at that time.
Linessa 21 Advisory	Aspen Pharmacare Canada Inc. recalled one lot (lot 200049, expiry 03/2023) of Linessa 21 (DIN 02272903), a prescription birth control pill, due to missing and mispackaged pills. Some blister packs may be missing pills, may contain more than one tablet in a blister pocket, or may contain pills in the wrong order.
Medtronic Heartware Ventricular Assist Device (HVAD™) System Health Professional Risk Communication Medical Device Recall	The Medtronic HVAD™ System was recalled due to an increased risk of neurological adverse events and mortality, as well as a potential for the internal pump of the Medtronic HVAD™ System to delay or fail to restart.

Non-steroidal anti-inflammatory drugs Advisory	Health Canada completed a safety review confirming that the use of non-steroidal anti-inflammatory drugs (NSAIDs) starting from approximately 20 weeks of pregnancy or later, may cause rare, but serious, kidney problems in an unborn baby. This can lead to low levels of amniotic fluid and possible complications, such as impaired lung maturation and loss of joint movement (limb contractures) in the newborn baby. As a result of its findings, Health Canada is advising that pregnant women not use NSAIDs from approximately 20 to 28 weeks of pregnancy, unless advised to do so by their healthcare professional. Prescription and non-prescription NSAID product labels will be updated with this new information. The use of NSAIDs remains contraindicated in the last trimester of pregnancy (i.e., beyond 28 weeks to the end of pregnancy).
Renadyl probiotic capsules Advisory	Gelda Scientific and Industrial Development Corporation recalled all lots of Renadyl probiotic capsules due to an undeclared ingredient (inulin) and missing important safety warnings from the product label.
Ruzurgi (amifampridine) Health Professional Risk Communication	A new Notice of Compliance (NOC) for Ruzurgi (amifampridine) was issued on June 24, 2021. Ruzurgi is, therefore, authorized for sale again in Canada. Ruzurgi is indicated for the symptomatic treatment of Lambert-Eaton myasthenic syndrome (LEMS) in patients 6 years of age and older.
Yummy Sports Candies BCAA powder Advisory	Yummy Sports Candies BCAA powder (all flavours, NPN 80097035) has been recalled by 10592706 Canada Inc. because the product label is missing an important statement warning that pregnant or breastfeeding women should consult a healthcare provider before using this product.

NEW HEALTH PRODUCT SAFETY INFORMATION

The following topics have been selected to raise awareness and, in some cases, to stimulate reporting of similar adverse reactions.

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 of the details of the drug and the nature 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 in accordance with the NOC/c policy. For the most up-to-date information, consult Health Canada's NOC database.

Gavreto (pralsetinib): Authorization with conditions

Health Canada has issued a Notice of Compliance, under the Notice of Compliance with Conditions policy, for Gavreto (pralsetinib), capsules, 100mg. Gavreto is indicated for the treatment of adult patients with rearranged during transfection (*RET*) fusion-positive locally advanced unresectable or metastatic non-small cell lung cancer. Patients should be advised about the conditional market authorization for this indication.

For the complete prescribing information and information available for the patients/caregivers, please consult the Gavreto Canadian product monograph. The product monograph can be accessed through Health Canada's Drug Product Database, the Hoffmann-La Roche Limited website or by contacting Hoffmann-La Roche Limited at 1-888-762-4388. Contact the company for a copy of any references, attachments or enclosures.

Retevmo (selpercatinib): Authorization with conditions

Health Canada has issued a Notice of Compliance, under the Notice of Compliance with Conditions policy, for Retevmo (selpercatinib), capsules, 40mg and 80mg. Retevmo is indicated as monotherapy for the treatment of metastatic *RET* fusion-positive non-small cell lung cancer in adult patients, *RET*-mutant medullary thyroid cancer in adult and pediatric patients 12 years of age and older with unresectable advanced or metastatic disease, and *RET* fusion-positive differentiated thyroid carcinoma in adult patients with advanced or metastatic disease (not amenable to surgery or radioactive iodine therapy) following prior treatment with sorafenib and/or lenvatinib. Patients should be advised about the conditional market authorization for this indication.

For the complete prescribing information and information available for the patients/caregivers, please consult the Retevmo Canadian product monograph. The product monograph can be accessed through Health Canada's Drug Product Database, the Eli Lilly Canada Inc. website or by contacting Eli Lilly Canada Inc. at 1-888-545-5972. 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
- Drug and vaccine authorizations for 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 HC.infowatch-infovigilance.SC@canada.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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