Health Canada Santé Canada

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

Health Product InfoWatch

March 2020

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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
Direct-acting antivirals
Kyprolis (carfilzomib)
Metformin
Rozlytrek (entrectinib)

Natural health products
Performance Plus capsules

Other
Unauthorized health products

ANNOUNCEMENTS

Coronavirus disease (COVID-19): updates

For updates on the Coronavirus disease (COVID-19), visit Canada.ca/coronavirus. This Web page includes a dedicated section for healthcare professionals.

Health Canada has announced a number of COVID-19 related notices relevant to drugs and medical devices:

Optimizing the use of masks and respirators during the COVID-19 outbreak [2020-03-24]

List of diagnostic devices for use against coronavirus (COVID-19) [2020-03-23]

Management of clinical trials during the COVID-19 pandemic: Notice to clinical trial sponsors [2020-03-23]

Notice for Industry: Mandatory Reporting Requirement during the COVID-19 Pandemic [2020-03-23]

Notice for Hospitals: Mandatory Reporting Requirement during the COVID-19 Pandemic [2020-03-23]

Notice: Expedited Review of Health Product Submissions and Applications to address COVID-19 [2020-03-18]

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.

Health Product InfoWatch 2015 - 2020 5 years

Canada

ANNOUNCEMENTS (CONTINUED)

Health Canada's new Medical Device Directorate

The Health Products and Food Branch has created a new, stand-alone Medical Devices Directorate. The new Directorate will take a life cycle approach to regulating medical devices for human use.

For more information, please visit the new Medical Devices Directorate Web page.

MONTHLY RECAP OF HEALTH PRODUCT SAFETY INFORMATION

The following is a list of health product advisories, type I recalls as well as summaries of completed safety reviews published in February 2020 by Health Canada.

Direct-acting antivirals Summary Safety Review	This safety review evaluated the risk of dysglycemia associated with direct-acting antivirals (DAAs). Health Canada's review concluded that there is a link between DAAs and dysglycemia, with evidence supporting the link between DAAs and hypoglycemia in diabetic patients. Health Canada is working with the manufacturers to update the Canadian product monographs for DAAs to inform about this risk.
Metformin Information Update Drug recalls: APO-Metformin Jamp-Metformin RAN-Metformin	Apotex Inc., Ranbaxy Pharmaceuticals Canada Inc. and JAMP Pharma Corporation have recalled certain lots of APO-Metformin ER, RAN-Metformin and Jamp-Metformin respectively. The affected lots contain or may contain N-nitrosodimethylamine (NDMA) above the acceptable limit. The *Affected products* table in the Information Update provides information on the recalled lots.
Performance Plus capsules Advisory	Health Canada has suspended the product licence for Performance Plus capsules (NPN 80053999) because it may pose serious health risks, such as heart attack and stroke. Performance Plus is distributed by TW Trade and promoted as a natural health product for sexual enhancement. Health Canada laboratory testing found that it contains sildenafil, which is not listed on the product label.
Unauthorized health products Multiple unauthorized health products Unauthorized skin lightening health products	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 topics have been selected to raise awareness and, in some cases, to stimulate reporting of similar adverse reactions.

PRODUCT MONOGRAPH UPDATES

The following safety labelling updates, which were recently made to the Canadian product monograph, have 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. Canadian product monographs can be accessed through Health Canada's Drug Product Database.

Kyprolis (carfilzomib)

The risks of **hepatitis B virus (HBV) reactivation** and **progressive multifocal leukoencephalopathy (PML)** have been included in the *Warnings and Precautions*, *Adverse Reactions (Post-Market Adverse Drug Reactions)* and *Patient Medication Information* sections of the Canadian product monograph for Kyprolis.

Key messages for healthcare professionals:[1]

HBV reactivation:

- Cases of HBV reactivation have been reported in patients receiving Kyprolis.
- Patients should be tested for HBV infection before initiating treatment. For patients who are carriers of HBV, prophylaxis with antivirals should be considered before, throughout, and for at least 6 months after the end of the treatment.
- Carriers of HBV who require treatment with Kyprolis should be closely monitored for signs and symptoms of active HBV infection (jaundice, abdominal pain, joint pain, weakness and fatigue, nausea and vomiting) throughout and following the end of treatment. Consider consulting a specialist for patients who test positive for HBV infection prior to or during treatment.
- The safety of resuming Kyprolis after HBV reactivation is adequately controlled, is not known. Therefore, prescribers should weigh the risks and benefits when considering resumption of therapy in this situation.

PML:

- Cases of PML (blurred or double vision, blindness, aphasia, muscle weakness, coordination and gait difficulties, persistent numbness, sensory deficit, cognitive dysfunction) have been reported in patients treated with Kyprolis who have had prior or concurrent immunosuppressive therapy.
- Patients should be monitored for any new or worsening neurologic, cognitive or behavioural signs or symptoms that may be suggestive of PML as part of the differential diagnosis of central nervous system disorders. If PML is suspected, patients should be promptly referred to a specialist and appropriate diagnostic testing should be initiated. Kyprolis should be discontinued if PML diagnosis is confirmed.

Reference

1. *Kyprolis (carfilzomib)* [product monograph]. Mississauga (ON): Amgen Canada Inc.; 2020.

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 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.

Rozlytrek (entrectinib): Authorization with conditions

Health Canada has issued a Notice of Compliance, under the Notice of Compliance with Conditions policy for Rozlytrek (entrectinib), capsules, 100 mg and 200 mg. Rozlytrek is indicated for the treatment of adult patients with unresectable locally advanced or metastatic extracranial solid tumours, including brain metastases, that have a neurotrophic tyrosine receptor kinase (NTRK) gene fusion without a known acquired resistance mutation, and with no satisfactory treatment options. 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 Rozlytrek Canadian product monograph. The product monograph can be accessed through Health Canada's Drug Product Database, the Hoffmann-La Roche Limited Web site or by contacting Hoffmann-La Roche Limited at 1-888-762-4388. 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
- Annual trends for adverse reaction case reports and medical device problem incidents
- Stop Illegal Marketing of Drugs and Devices

Suggestions?

Your comments are important to us. Let us know what you think by reaching us at HC.infowatch-infovigilance.SC@canada.ca

Health Canada
Marketed Health Products Directorate
Address Locator 1906C
Ottawa ON K1A 0K9
Telephone: 613-954-6522
Fax: 613-952-7738

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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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