Health Canada Santé Canada

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

Health Product InfoWatch

April 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

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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
- Hydrea (hydroxyurea)
- Methadone
- Opdivo (nivolumab)
- Rifampin
- Taro-Zoledronic acid injection

Medical devices
- Bluetooth Low Energy chips in some medical devices
- Personal Protective Equipment
- Swabs

Natural and non-prescription health products
- Disinfectants
- Hand sanitizers
- Ibuprofen

Other
- False or misleading claims
- Stockpiling drugs
- Unauthorized health products

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.

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

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 March 2020 by Health Canada.

Disinfectants, hand sanitizers, personal protective equipment and swabs for COVID-19 Advisory	Health Canada facilitated access to products that can help limit the spread of COVID-19 that may not fully meet current regulatory requirements, as an interim measure. This includes hand sanitizers, disinfectants and personal protective equipment (such as masks and gowns), as well as swabs.
False or misleading claims to prevent, treat or cure COVID-19 Advisory	Health Canada warned Canadians about the risks of buying health products—including drugs, natural health products, homeopathic products, and medical devices—that make false or misleading claims to prevent, treat or cure COVID-19. The Government of Canada has published a list of hand sanitizers and disinfectants that meet Health Canada's requirements, and provides guidance on the use of masks and respirators during the COVID-19 outbreak. Canadians should check the online list (products accepted for sale in Canada under the interim measure) to confirm whether the product they are purchasing has been notified to Health Canada.
Ibuprofen in COVID-19 cases Information Update	There is no scientific evidence that establishes a link between ibuprofen, or other non-steroidal anti-inflammatory drugs, and the worsening of COVID-19 symptoms. The Government of Canada is monitoring the situation closely, including reviewing new information and reports as they become available, and will take the appropriate action to help protect the health and safety of Canadians.
Medical devices with Bluetooth Low Energy chips Information Update	A series of cybersecurity vulnerabilities named "SweynTooth" may affect devices using the Bluetooth Low Energy (BLE) protocol. Because of these vulnerabilities, some medical devices that use BLE chips could be at risk of a cyber-attack. Affected medical devices may include pacemakers, blood glucose monitors, ultrasound systems and insulin pumps.
Methadone Health Professional Risk Communication	Health Canada has received reports from patients and healthcare professionals that there may be variations in how patients respond to different formulations of methadone when used for opioid substitution treatment in opioid drug dependence. Some patients may experience withdrawal symptoms after being switched from one formulation to another.
Rifampin Advisory	Bausch Health, Canada Inc. released a limited number of lots of its tuberculosis drug rifampin (Rofact), to mitigate a national shortage. Although these lots contain slightly higher than acceptable levels of a nitrosamine impurity, the risks of not being treated immediately are greater than would result from short-term use of the drug.

Stockpiling drugs during COVID-19 Advisory	Health Canada urged Canadians to avoid stockpiling drugs and called on health professionals to avoid prescribing or dispensing larger supplies of medication than necessary. Increased demand and stockpiling of medications can lead to local shortages. Health Canada is monitoring the supply situation closely and will take any necessary actions in collaboration with companies, provinces and territories, healthcare professionals, and our international regulatory partners to help ensure continued supply of medications for Canadians.
Taro-Zoledronic acid injection Advisory Drug recall	Taro Pharmaceuticals Inc. recalled 5 lots of Taro-Zoledronic acid injection 5mg/100mL (DIN 02415100) because of the potential presence of particulate matter in the drug.
Unauthorized health products Multiple unauthorized health products Unauthorized skin lightening products from Blue Sky Supermarket Unauthorized skin lightening product from Danforth Variety & Fruit Market	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.

Hydrea (hydroxyurea)

The risk of **interstitial lung disease** has been included in the *Warnings, Adverse Drug Reactions,* and *Consumer Information* sections of the Canadian product monograph for Hydrea.

In addition, reports of tumour responses to Hydrea in melanoma have been removed from the *Indications and Clinical Use* section for Hydrea. Hydrea is indicated for concomitant use with irradiation therapy in the treatment of primary squamous cell (epidermoid) carcinomas of the head and neck, excluding the lip. Tumour responses to Hydrea have been reported in resistant chronic myelocytic leukemia.

Key messages for healthcare professionals:[1]

- Interstitial lung disease including pulmonary fibrosis, lung infiltration, pneumonitis, and alveolitis/ allergic alveolitis (including fatal cases) have been reported in patients treated with Hydrea for myeloproliferative neoplasm.
- Patients developing pyrexia, cough, dyspnea, or other respiratory symptoms should be closely monitored, investigated and treated. Hydroxyurea should be promptly discontinued and patients should be treated with corticosteroids to resolve the pulmonary events.

Reference

1. *Hydrea (hydroxyurea)* [product monograph]. Montreal (QC): Bristol-Myers Squibb Canada Co.; 2020.

Opdivo (nivolumab)

The *Warnings and Precautions* and *Dosage and Administration* sections of the Canadian product monograph for Opdivo (nivolumab) have been updated to include additional guidance on monitoring, testing and management of **myocarditis** for Opdivo, when used alone or in combination with Yervoy (ipilimumab).

Key messages for healthcare professionals:[1]

- Cases of myocarditis, some with fatal outcome, have been reported with Opdivo or Opdivo combined with Yervoy. As some cases may be asymptomatic, a diagnosis of myocarditis requires a high index of suspicion.
- Patients with cardiac or cardiopulmonary symptoms should undergo a prompt diagnostic workup for myocarditis with close monitoring. If myocarditis is suspected, prompt initiation of a high dose of steroids (prednisone or methylprednisolone 1 to 2 mg/kg/day), and prompt cardiology consultation with diagnostic workup, including electrocardiogram, troponin assay and echocardiogram should be initiated. Additional testing may be warranted, as guided by a cardiologist, and may include cardiac magnetic resonance imaging.
- Once a diagnosis is established, Opdivo or Opdivo in combination with Yervoy should be withheld. Opdivo or Opdivo/Yervoy combination therapy should be permanently discontinued in patients with grade 3 myocarditis.

Reference

1. *Opdivo (nivolumab)* [product monograph]. Montreal (QC): Bristol-Myers Squibb Canada Co.; 2020.

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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