Health Canada Santé Canada

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

Health Product InfoWatch

August 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

- Brilinta (ticagrelor)
- Cabazitaxel products
- Cetrotide (cetrorelix for injection)
- DDAVP Spray (desmopressin acetate)
- Methadone
- Picato (ingenol mebutate)
- Ranitidine
- Singulair (montelukast)
- Veklury (remdesivir)

Natural and Non-prescription Health Products

- Certain hand sanitizers that contain technical-grade ethanol
- Certain hand sanitizers that may pose health risks
- Codeine-containing non-prescription analgesics

Other

- Counterfeit respirators

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

Did you know?

Cabazitaxel products with different instructions for dilution

In Canada, some cabazitaxel products are now available at an initial concentration of 10 mg/mL. These cabazitaxel products only require 1 dilution rather than the 2 dilution steps required for products with a concentration of 40 mg/mL. Attention is required when preparing cabazitaxel products to ensure that the appropriate dilution instructions are followed. Hospitals, cancer centers, compounding pharmacies and other facilities preparing chemotherapy products may need to amend their preparation protocols to ensure the correct dilution instructions and concentration are reflected for the product in use for accurate preparation of cabazitaxel.

To access the list of cabazitaxel products available in Canada and their respective concentration and dilution instructions, please visit the Drug Product Database.

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 July 2020 by Health Canada.

Brilinta (ticagrelor) Summary Safety Review	This safety review evaluated the risk of bradyarrhythmia and second-and third-degree atrioventricular (AV) block associated with Brilinta. Health Canada's review concluded that there may be a link between the use of Brilinta and the risk of bradyarrhythmia, including second and third-degree AV block. Health Canada will work with the manufacturer to update the Canadian product monograph for Brilinta to inform healthcare professionals and patients about these risks.
Certain hand sanitizers that contain technical-grade ethanol Advisory	Health Canada advised Canadians that certain hand sanitizers containing technical-grade ethanol were recalled from the market because they are not compliant with federal regulations and may pose a risk to health.
Certain hand sanitizers that may pose health risks Advisory	Health Canada advised Canadians that certain hand sanitizers were recalled from the market because they contain types of ethanol or denaturants that are not acceptable ingredients for use in hand sanitizers in Canada.
Cetrotide (cetrorelix for injection) Advisory Drug Recall	One lot of Cetrotide 0.25mg (Lot 8J025C) was recalled because some vials may have missing stoppers, which could make the product unsterile. In addition, some of the contents of the vial may have spilled out because of the missing stopper, so the patient may not receive the proper dose and the drug would not be as effective. Health Canada will monitor the company's recall and inform Canadians if new safety information becomes available.

Codeine-containing non-prescription analgesics Advisory	Health Canada advised Canadians that people under 18 years of age should not use codeine-containing non-prescription analgesics. A review of all available information on these products demonstrated that using opioids at a young age may contribute to the development of problematic substance use later in life. Health Canada is working with manufacturers to update their product safety information to include this recommendation.
Counterfeit respirators Advisory	Health Canada has identified counterfeit respirators in Canada and advised consumers to stop using them as they may not protect Canadians against the virus that causes COVID-19. A table of counterfeit respirators is provided in the advisory, and will be updated on a regular basis as Health Canada obtains new information.
DDAVP Spray (desmopressin acetate) Advisory Drug Recall	Three lots of DDAVP Spray were recalled because the product may contain a higher than labelled dose of desmopressin and could pose an overdose risk. Health Canada will monitor the company's recall and inform Canadians if new safety information becomes available.
Methadone Health Professional Risk Communication Summary Safety Review	This safety review evaluated the risk of lack of effect when switching between different methadone products used for the treatment of opioid dependence. Health Canada's review found there may be a link, which may present as drug withdrawal, when switching between methadone-containing products, although the reason for this is unclear. Patients experiencing withdrawal symptoms after being switched from one methadone-containing product to another need to be seen by their healthcare professional and may need an adjustment in the dose of methadone. Health Canada will be working with manufacturers to update the Canadian product monographs to warn of this potential safety issue. Health Canada has also communicated this information to healthcare professionals.
Picato (ingenol mebutate) Information Update Summary Safety Review	This safety review evaluated the risk of skin cancer associated with Picato. Health Canada's review found that there may be a link. Health Canada will ask for additional information from the manufacturer to determine whether the benefits of Picato as a treatment option for actinic keratosis continue to outweigh its risks. Health Canada has also communicated this information to Canadians.
Ranitidine Advisory	Health Canada provided an update on the status of ranitidine drugs in Canada, including enhanced safety measures the Department is putting in place to detect the impurity N-nitrosodimethylamine (NDMA).

Veklury (remdesivir)

Advisory
Health Product InfoWatch

Health Canada has authorized with conditions the drug Veklury (remdesivir) for the treatment of patients (aged 12 years and older with a body weight of at least 40 kg) with severe symptoms of COVID-19 who have pneumonia and require extra oxygen.

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 page. Canadian product monographs can be accessed through Health Canada's Drug Product Database.

Singulair (montelukast)

The risk of **serious neuropsychiatric events** has been included in the *Serious Warnings and Precautions Box* in the Canadian product monograph for Singulair. The *Warnings and Precautions, Adverse Reactions, Dosage and Administration*, and *Consumer Information* sections of the Canadian product monograph for Singulair have also been updated in relation to this issue.

Key messages for healthcare professionals:[1]

- Serious neuropsychiatric (NP) events have been reported in patients with and without a previous history of psychiatric disorder during Singulair treatment and after its discontinuation. The mechanisms underlying NP events associated with Singulair use are currently not well understood.
- Highly variable NP event types were reported with the use of Singulair including, but not limited to, agitation, aggression, depression, sleep disturbances, suicidal thoughts and behaviour (including suicide).
- The benefits of Singulair may not outweigh the risks in some patients due to the risk of serious NP events, particularly when the symptoms of the disease may be mild and adequately treated with alternative therapies.
- The use of Singular should be reserved for patients with allergic rhinitis who have an inadequate response or intolerance to alternative therapies. In patients with asthma or exercise-induced bronchoconstriction, healthcare professionals should consider the benefits and risks before prescribing Singulair.
- Although in many cases NP symptoms resolved after stopping Singulair therapy, in some cases symptoms persisted after discontinuation of Singulair. Patients should be monitored and provided supportive care until NP symptoms resolve.
- Healthcare professionals are reminded to advise patients and/or caregivers to:
    - be alert for changes in behaviour or new NP symptoms when taking Singulair;
    - discontinue Singulair and contact a healthcare professional immediately if changes in behaviour are observed, or if new NP symptoms or suicidal thoughts and/or behaviour occur.

Reference

1. *Singulair (montelukast)* [product monograph]. Kirkland (QC): Merck Canada Inc.; 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
- Stop Illegal Marketing of Drugs and Devices
- List of Drugs for Exceptional Importation and Sale

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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