Health Canada Santé Canada

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

Health Product InfoWatch

January 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

Pharmaceuticals and Biologics

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Natural and Non-prescription Health Products

- Hand sanitizers that may pose health risks

Other

- Personal protective equipment sold by Maskopia
- Potential counterfeit COVID-19 vaccines

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

DID YOU KNOW?

The COVID-19 vaccines and treatments regulatory portal provides information for consumers, healthcare professionals and researchers on vaccines and treatments authorized for COVID-19, as well as those currently under review. The portal complements the information on the Canada.ca/coronavirus website.

https://covid-vaccine.canada.ca/

DRUG AND VACCINE AUTHORIZATIONS FOR COVID-19

The Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19 (the Interim Order) allows for the issuance of an expedited authorization for the importation, sale and advertising of drugs used in relation to COVID-19; this includes both human and veterinary drugs. The Interim Order introduces expedited authorization pathways for drugs with a COVID-19 indication that are not yet authorized in Canada or other jurisdictions; as well as COVID-19 drugs that are authorized for sale by a foreign regulatory authority. In addition, the Interim Order provides a mechanism to permit the sale of a drug that is already authorized in Canada under this Interim Order or the Food and Drug Regulations, for indications related to COVID-19 that are not included in the drug's authorization.

Moderna COVID-19 Vaccine (mRNA-1273 SARS-CoV-2 vaccine): Authorization with terms and conditions

Health Canada has authorized with terms and conditions, under the Interim Order, Moderna COVID-19 Vaccine (mRNA-1273 SARS-CoV-2 vaccine), suspension for intramuscular injection, multiple dose vial (contains 10 doses of 0.5 mL) for use in relation to COVID-19.

Moderna COVID-19 Vaccine is indicated for active immunization against coronavirus disease 2019 (COVID-19) caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 years of age and older.

For the complete prescribing information and information available for patients/caregivers, please consult the Moderna COVID-19 Vaccine Canadian product monograph. The product monograph can be accessed through Health Canada's Drug Product Database, the government's covid-vaccine.canada.ca website, at https://www.modernacovid19global.com/ca/, or by contacting Moderna Therapeutics Inc. at 1-866-MODERNA (1-866-663-3762). Contact the company for a copy of any references, attachments or enclosures.

COVID-19 vaccines and treatments portal: Moderna COVID-19 Vaccine

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 December 2020 by Health Canada.

Bacitracin for Injection Health Professional Risk Communication Summary Safety Review	This safety review evaluated the risk of nephrotoxicity and anaphylactic reactions associated with bacitracin for injection products. Health Canada's review found a possible link. Bacitracin for injection products are now contraindicated in patients with impaired renal function, including those taking nephrotoxic drugs. Health Canada is working with the manufacturers of bacitracin for injection products to update the Canadian product monographs to further strengthen the information about nephrotoxicity and to include information about anaphylactic reactions. This information has also been communicated to healthcare professionals.
Bamlanivimab Health Professional Risk Communication	Bamlanivimab was authorized for use in relation to the COVID-19 pandemic, in accordance with the Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19. To provide earlier access to the product in the context of the global pandemic, Lilly will distribute one standard package worldwide with English-only labelling. Important Canadian-specific information is absent from the vial and carton labels.
Carboplatin-containing products Summary Safety Review	This safety review evaluated the risk of posterior reversible encephalopathy syndrome (PRES) associated with carboplatin-containing products. Health Canada's review of the available information concluded that there may be a link. Health Canada will work with manufacturers to update the Canadian product monographs for carboplatin-containing products to include the risk of PRES.
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 or were not properly labelled and were missing important information.
Clobazam-containing products Summary Safety Review	This safety review evaluated the risk of drug reaction with eosinophilia and systemic symptoms (DRESS) associated with clobazam-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 clobazam-containing products to include the risk of DRESS.

Dexrazoxane for Injection, US-labelled Health Professional Risk Communication	Due to a shortage of Zinecard (Dexrazoxane for Injection) in Canada and given the medical necessity of this product, Health Canada has expressed no objection to the temporary importation and distribution of US-labelled Dexrazoxane for Injection. The US-labelled Dexrazoxane for Injection has the same active ingredient, strength (250 mg/vial), and concentration after reconstitution (10 mg/mL) as the Canadian-labelled product. However, there are key differences in the preparation instructions.
Direct-acting antiviral products containing a protease inhibitor Summary Safety Review	This safety review evaluated the risk of hepatic decompensation and hepatic failure associated with direct-acting antiviral products containing a protease inhibitor in some patients with pre-existing significant liver disease. Health Canada's review concluded that there may be a link. Health Canada requested that manufacturers of direct-acting antiviral products containing a protease inhibitor update the Canadian product monographs to include information about these risks.
Elmiron (pentosan polysulfate sodium) Health Professional Risk Communication	Cases of pigmentary maculopathy have been reported with long-term use of Elmiron. Elmiron is now contraindicated in patients with a personal history of any macular pathology. The Canadian product monograph for Elmiron has been updated to include the new contraindication and further strengthen the information about the risk of pigmentary maculopathy.
GUM Paroex Advisory Drug Recall	Sunstar Americas Inc. expanded its recall for its prescription anti-gingivitis oral rinse, GUM Paroex (DIN 02384272), to all lots on the Canadian market. The additional lots were recalled, as a precaution, because they may be contaminated with the bacteria *Burkholderia lata. Burkholderia lata* is a multidrug-resistant bacteria that has a high potential to cause serious respiratory and other infections in patients with underlying illnesses, such as cystic fibrosis and chronic granulomatous disease, or who are immunocompromised.
Moderna COVID-19 Vaccine Health Professional Risk Communication	Moderna COVID-19 Vaccine was authorized with terms and conditions for use in accordance with the Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19. As an extraordinary measure to provide earlier access to vaccine supplies in the context of the global pandemic, Moderna is providing, at this time, vaccine vials and cartons labelled with the global label. This label is presented in English-only and is missing some important Canadian-specific information normally found on Health Canada approved labels.

Personal protective equipment sold by Maskopia Advisory	Health Canada warned Canadians that the company Maskopia (formerly known as Medkem Canada Inc.) in Brampton, Ontario, had been selling personal protective equipment, including gowns, masks and gloves, via social media and websites such as Kijiji without the required Medical Device Establishment Licence from Health Canada. Canadians are advised to immediately stop using these products and to dispose of them as they may not provide the level of protection advertised due to unknown quality and safety.
Pfizer-BioNTech COVID-19 Vaccine Health Professional Risk Communication	Pfizer-BioNTech COVID-19 Vaccine was authorized with terms and conditions for use in accordance with the Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19. As an extraordinary measure to provide earlier access to vaccine supplies in the context of the global pandemic, Pfizer/BioNTech is providing, at this time, vaccine cartons and vials labelled with the US Emergency Use label. This label is presented in English-only and is missing some important Canadian-specific information normally found on Health Canada approved labels.
Pfizer-BioNTech COVID-19 Vaccine – recommendations for people with serious allergies Advisory	Two individuals in the UK reported severe allergic reactions to Pfizer-BioNTech's COVID-19 vaccine on December 8, 2020. People with allergies to any of the ingredients of the vaccine are currently cautioned against receiving it. This caution is noted in the Canadian product monograph for the Pfizer-BioNTech COVID-19 vaccine. Healthcare professionals should follow guidance and recommendations related to identifying and managing serious allergic reactions following immunization. This includes ensuring that appropriate medical treatment and supervision are in place at all vaccination sites, as indicated in the product monograph. Health Canada continues to work with the UK Medicines and Healthcare products Regulatory Agency and with the manufacturer to monitor the situation. Health Canada will take action if any new safety issues are confirmed.
Potential counterfeit COVID-19 vaccines Advisory	Health Canada warned Canadians about the risks of buying COVID-19 vaccines sold on the internet or from unauthorized sources as they are counterfeit and may pose serious health risks.
Tramadol-containing products Summary Safety Review	This safety review evaluated the risk of hallucinations associated with tramadol-containing products. Health Canada's review of the available information established a link between the use of tramadol-containing products, at normal doses, and the risk of visual and auditory hallucinations, especially in patients over 65 years of age. Health Canada will work with manufacturers to update the Canadian product monographs for tramadol products to include this risk.

HEALTH CANADA NEWS

Health Canada proposes lowering the nicotine concentration limit in vaping products

In an effort to reduce the appeal of vaping products, Health Canada is proposing regulations to set a maximum nicotine concentration of 20 mg/mL for vaping products (from the current 66 mg/mL). The proposal also seeks to prohibit the packaging and sale of a vaping product if the nicotine concentration displayed on the package exceeds this new limit.

A public consultation will be open for comments until March 4, 2021.

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

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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