Health Canada Santé Canada

Canada

Health Product InfoWatch

September 2022

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pms-Hydromorphone

Sodium chloride 23.4% injection

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Taro-Zoledronic acid injection

Other

Unauthorized health products

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.

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.

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.

The COVID-19 vaccines and treatments portal provides information for consumers, healthcare professionals and researchers on vaccines and treatments authorized for COVID-19.

For information about adverse events following immunization that individuals have reported after receiving a COVID-19 vaccine in Canada, new safety signals or other safety updates, please visit the COVID-19 vaccine safety in Canada webpage.

DRUG AND VACCINE AUTHORIZATIONS AND COMMUNICATIONS FOR COVID-19

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

Comirnaty (Pfizer-BioNTech COVID-19 Vaccine)

On September 9, 2022, Health Canada authorized a new presentation of Comirnaty (COVID-19 Vaccine, mRNA), 3 mcg/0.2 mL (DIN 02530325), for use in children aged 6 months to less than 5 years. This new presentation has a MAROON vial cap and MAROON label border. It requires dilution with 2.2 mL of sterile 0.9% Sodium Chloride Injection, USP prior to use.

In addition, as an extraordinary measure to provide access to vaccine supplies in the context of the global pandemic, Pfizer and BioNTech are continuing to provide vaccine supplies with vials and cartons labelled with the name Pfizer-BioNTech COVID-19 Vaccine. This label is presented in English only and is missing some important Canadian-specific information normally found on Health Canada approved labels.

Health Product Risk Communication

On August 19, 2022, Health Canada authorized a booster dose of Comirnaty for children aged 5 through <12 years of age. A booster dose of Comirnaty (0.2 mL) may be administered intramuscularly at least 6 months after completion of the primary series in individuals 5 through <12 years of age.

Authorization with terms and conditions

Spikevax Bivalent (elasomeran/imelasomeran) COVID-19 Vaccine

On September 1, 2022, Health Canada authorized Spikevax Bivalent (elasomeran/imelasomeran), which targets the original SARS-CoV-2 virus from 2019 and the Omicron (BA.1) variant, for use as a booster dose in individuals 18 years of age or older.

In order to provide rapid access to Spikevax Bivalent, Moderna is distributing product vials and cartons labelled in English only with the brand name "Spikevax 0 (Zero) / O (Omicron)" for a period of time. Important Canadian-specific information is absent from these labels. The bivalent Spikevax 0 (Zero) / O (Omicron), 0.10 mg/mL, 2.5 mL shares the same coloured vial cap (royal blue) to monovalent Spikevax 0.10 mg/mL, 2.5 mL.

Health Product Risk Communication
Authorization with terms and conditions

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 August 2022 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.

Draximage MDP Type 1 drug recall	One lot of Draximage MDP has been recalled because it may contain particulate matter.
Imbruvica (ibrutinib) Health Product Risk Communication	Serious and fatal events of cardiac arrhythmia or cardiac failure have occurred in patients treated with Imbruvica. Patients with significant cardiac co-morbidities may be at greater risk for developing these events, including sudden fatal cardiac events. Responding to data from new clinical trials and the ongoing monitoring of product safety, the Canadian product monograph for Imbruvica has been updated to include stronger warnings about these cardiac-related events and new dose modification guidelines.
Jamp-Atorvastatin Advisory	Jamp Pharma Corporation recalled one lot of Jamp-Atorvastatin 40 mg tablets due to possible contamination with latex pieces during manufacturing. A piece of latex was found in one tablet from the affected lot.

Jamp-Atorvastatin Calcium Advisory	Jamp Pharma Corporation recalled one lot of Jamp-Atorvastatin Calcium after one bottle labelled to contain 10 mg tablets of Jamp-Atorvastatin Calcium was found to contain 40 mg tablets of Jamp-Atorvastatin Calcium. Product from the affected lot was sold to pharmacies between May 2022 and August 2022.
Nexavar (sorafenib) Summary Safety Review	This safety review evaluated the risk of thrombotic microangiopathy with the use of Nexavar (sorafenib). Health Canada's review concluded that there may be a link. Health Canada will work with the manufacturer to update the Canadian product monograph for Nexavar to include this risk.
Normosol-R Type 1 drug recall	One lot of Normosol-R solution bags has been recalled, as the bags in the affected lot may be leaking.
pms-Hydromorphone Advisory	Pharmascience Inc. recalled one lot of pms-Hydromorphone, 2 mg tablets, as the bottles may contain hydromorphone tablets of a different strength (8 mg). Products from the affected lot were sold between May 2022 and August 2022.
Sodium chloride 23.4% injection Type 1 drug recall	Several lots of Sodium chloride 23.4% injection (Omega Laboratories Limited) have been recalled, as the affected lots may contain glass particles.
Taro-Zoledronic acid injection Advisory	Taro Pharmaceuticals Inc. recalled all lots of Taro-Zoledronic acid injection 5mg/100mL because they may contain particulate matter.
Unauthorized health products Advisory: Counterfeit COVID-19 antigen rapid test kits found in Ontario Advisory: Counterfeit Viagra and Cialis erectile dysfunction drugs seized from Grace Daily Mart in Scarborough, Ontario Advisory: Unauthorized health products seized from Productos Latinos El Aguila in Leamington, Ontario Advisory: Unauthorized products may pose serious health risks	Health Canada advised Canadians about various unauthorized health products being sold at retail locations across Canada or online that may pose serious health risks.

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
- Medical device shortages: List of shortages and discontinuations
- Stop Illegal Marketing of Drugs and Devices
- List of drugs for exceptional importation and sale
- 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:
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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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