Health Canada Santé Canada

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

Health Product InfoWatch

August 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

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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

AstraZeneca COVID-19 Vaccine
Casirivimab and Imdevimab
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Neutrogena Beach Defense and Ultra Sheer aerosol spray sunscreens

Other

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) 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

The COVID-19 vaccines and treatments portal provides information for consumers, healthcare professionals and researchers on vaccines and treatments authorized for COVID-19, as well as those currently under review.

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. This page is updated weekly.

DRUG AND VACCINE AUTHORIZATIONS AND COMMUNICATIONS FOR COVID-19

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

Casirivimab and Imdevimab

Casirivimab and imdevimab, to be administered together, were authorized for the treatment of mild to moderate coronavirus disease 2019 (COVID-19), confirmed by direct SARS-CoV-2 viral testing, in adults and adolescents (12 years of age and older weighing at least 40 kg) who are at high risk for progressing to hospitalization and/or death. To provide earlier access to the product in the context of the global pandemic, Hoffmann-La Roche will distribute one standard global pandemic packaging with English-only labelling.

Health Professional Risk Communication

COVID-19 Vaccine Moderna

Further to the Health Canada communication issued on June 14, 2021 (and updated on June 24, 2021), ModernaTx, Inc. is providing one additional lot (016F21A) of US-labelled vaccine supplies with English-only vial and carton labels in order to expedite the distribution of the vaccine in Canada.

Health Professional Risk Communication

PRODUCT MONOGRAPH UPDATES FOR COVID-19 VACCINES

The following safety labelling updates, which were recently made to the Canadian product monograph, have been selected for your awareness. Canadian product monographs for authorized vaccines and treatments for COVID-19 can be accessed through the COVID-19 vaccines and treatments portal or Health Canada's Drug Product Database.

AstraZeneca COVID-19 Vaccine and COVISHIELD

The *Warnings and Precautions, Adverse Reactions (Post-Market Adverse Reactions)*, and *Patient Medication Information* sections of the Canadian product monograph for the AstraZeneca COVID-19 Vaccine and COVISHIELD have been updated with the risk of **Guillain-Barré Syndrome.**

Key messages for healthcare professionals:[1,2]

- Very rare events of demyelinating disorders, such as Guillain-Barré Syndrome, have been reported following vaccination with AstraZeneca COVID-19 Vaccine or COVISHIELD during post-authorization use.
- Healthcare professionals should be alert to Guillain-Barré Syndrome signs and symptoms to ensure correct diagnosis, in order to initiate adequate supportive care and treatment, and to rule out other causes.

References

1. *AstraZeneca COVID-19 Vaccine (COVID-19 Vaccine (ChAdOx1-S [recombinant])* [product monograph]. Mississauga (ON): AstraZeneca Canada Inc.; August 13, 2021.
2. *COVISHIELD (COVID-19 Vaccine (ChAdOx1-S [recombinant])* [product monograph]. Mississauga (ON): Verity Pharmaceuticals Inc.; August 13, 2021.

Janssen COVID-19 Vaccine

The *Warnings and Precautions, Adverse Reactions (Post-Market Adverse Reactions)*, and *Patient Medication Information* sections of the Canadian product monograph for Janssen COVID-19 Vaccine have been updated with the risk of **Capillary Leak Syndrome, Guillain-Barré Syndrome** and **Thrombosis with Thrombocytopenia Syndrome**. The *Contraindications* section has also been updated with the risk of **Capillary Leak Syndrome**.

Key messages for healthcare professionals:[1]

Capillary Leak Syndrome

- Janssen COVID-19 Vaccine is contraindicated in individuals with a history of Capillary Leak Syndrome (CLS).
- Cases of CLS have been observed very rarely in the first days following vaccination with Janssen COVID-19 Vaccine during post-authorization use.

Guillain-Barré Syndrome

- Very rare events of demyelinating disorders, such as Guillain-Barré Syndrome, have been reported following vaccination with Janssen COVID-19 Vaccine during post-authorization use.
- Healthcare professionals should be alert to Guillain-Barré Syndrome signs and symptoms to ensure correct diagnosis, in order to initiate adequate supportive care and treatment, and to rule out other causes.

Thrombosis with Thrombocytopenia Syndrome

- A combination of thrombosis and thrombocytopenia, including thrombosis with thrombocytopenia syndrome, in some cases accompanied by bleeding, has been observed very rarely following vaccination with Janssen COVID-19 Vaccine during post-authorization use.

Reference

1. *Janssen COVID-19 Vaccine (SARS-CoV-2 Vaccine [Ad26.COV2.S, recombinant]* [product monograph]. Toronto (ON): Janssen Inc.; August 18, 2021.

Pfizer-BioNTech COVID-19 Vaccine

The *Adverse Reactions (Post-Market Adverse Reactions)* and *Patient Medication Information* sections of the Canadian product monograph for the Pfizer-BioNTech COVID-19 Vaccine has been updated to include the risk of **facial paralysis / Bell's Palsy.**[1] Health Canada has also communicated this information to Canadians.

Key messages for healthcare professionals:[1]

- Cases of facial paralysis / Bell's Palsy have been reported in a small number of people in Canada and internationally following vaccination.

Advisory – Pfizer-BioNTech COVID-19 Vaccine

Reference

1. *Pfizer-BioNTech COVID-19 Vaccine (COVID-19 mRNA Vaccine)* [product monograph]. Mainz (Germany): BioNTech Manufacturing GmbH; August 4, 2021.

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 July 2021 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.

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, were not properly labelled, were unauthorized, or were missing important information.
CPAP and BiLevel PAP machines and mechanical ventilators Advisory	Philips Respironics has recalled several models of its Continuous Positive Airway Pressure (CPAP) machines, BiLevel Positive Airway Pressure (BiLevel PAP) machines and mechanical ventilators in Canada and internationally. The devices include a foam component that reduces sounds from the device. This foam may degrade into particles which may be inhaled or swallowed by users, or release volatile organic compounds that may be inhaled.
Face masks that contain graphene Advisory	Health Canada assessed four models of face masks manufactured by Shandong Shengquan New Materials Co. Ltd. labelled to contain biomass graphene and found no health risks of concern. As a result, sale of these masks can resume in Canada. No other graphene face masks are currently permitted for sale in Canada. If additional graphene masks are permitted for sale, Health Canada will update Canadians.

Martin Clinic Liquid Vitamin D Advisory	All lots of Martin Clinic Liquid Vitamin D were recalled due to incorrect dosing instructions on the label that could lead to taking too much vitamin D. The label is also missing important warnings, including that the product is not for use by children under 12 years of age, and to consult a healthcare professional if taking blood thinners. The product is sold by Martin Clinic and Nutrition Centre online, and at their clinic and supplement store, which is located in Sudbury, Ontario.
Neutrogena Beach Defense and Ultra Sheer aerosol spray sunscreens Advisory	All lots of Neutrogena Beach Defense and Ultra Sheer children and adult sunscreens, in aerosol spray format, were recalled after testing detected elevated levels of benzene. Frequent and long-term exposure (e.g., through the skin and by inhalation) to elevated levels of benzene may pose serious health risks.
Unauthorized health products Advisory – Multiple unauthorized drugs from Tokyo Beauty in Burnaby, B.C. Advisory – Various unauthorized 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.

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
- 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 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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