Health Canada Santé Canada

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Health Product InfoWatch

March 2021

CONTENTS

REPORTING ADVERSE REACTIONS

Canada Vigilance Program
Online: Adverse Reaction and Medical Device Problem Reporting
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HEALTH PRODUCTS MENTIONED IN THIS ISSUE

Pharmaceuticals and Biologics

- Acetazolamide
- AstraZeneca COVID-19 Vaccine
- Ceftriaxone-containing products
- Chlorthalidone
- COVID-19 Vaccine Moderna
- COVISHIELD COVID-19 Vaccine
- Hydrochlorothiazide
- Indapamide
- Janssen COVID-19 Vaccine
- Metolazone
- Pfizer-BioNTech COVID-19 Vaccine
- Ranitidine
- Tecentriq (atezolizumab)

Natural and Non-prescription Health Products

- Acetaminophen
- Hand sanitizers that may pose health risks
- Perfect Sports Core Series Pure Creatine

Other

- Hand sanitizers and hard surface disinfectants
- 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

DID YOU KNOW?

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 please see visit the COVID-19 vaccine safety in Canada webpage. This page is updated weekly.

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.

AstraZeneca COVID-19 Vaccine: Authorization with terms and conditions

Health Canada has authorized with terms and conditions, under the Interim Order, AstraZeneca COVID-19 Vaccine (ChAdOx1-S [recombinant]), solution for intramuscular injection, multiple dose vial (contains 8 doses of 0.5 mL and 10 doses of 0.5 mL) for use in relation to COVID-19.

AstraZeneca COVID-19 Vaccine is indicated for active immunization of individuals 18 years of age and over for the prevention of coronavirus disease 2019 (COVID-19).

For the complete prescribing information and information available for patients/caregivers, please consult the AstraZeneca 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 www.AZCOVID-19.com, or by contacting AstraZeneca Canada Inc. at 1-800-668-6000. Contact the company for a copy of any references, attachments or enclosures.

COVID-19 vaccines and treatments portal – AstraZeneca COVID-19 Vaccine

AstraZeneca COVID-19 Vaccine: Statement

Health Canada confirmed that the benefits of the AstraZeneca COVID-19 Vaccine in protecting Canadians from COVID-19 continue to outweigh the risks. Health Canada has assessed the available data on the reported events and has determined that the AstraZeneca vaccine has not been associated with an increase in the overall risk of blood clots. Health Canada is aware of very rare reports in Europe of blood clots associated with thrombocytopenia. Health Canada will continue to work with international regulators and review data and evidence as it becomes available, and will take action to ensure that healthcare professionals and Canadians have the safety information they need.

Statement – AstraZeneca COVID-19 Vaccine

COVISHIELD COVID-19 Vaccine: Authorization with terms and conditions

Health Canada has authorized with terms and conditions, under the Interim Order, COVISHIELD COVID-19 Vaccine (ChAdOx1-S [recombinant]), solution for intramuscular injection, multiple dose vial (contains 10 doses of 0.5 mL) for use in relation to COVID-19.

COVISHIELD is indicated for active immunization of individuals 18 years of age and over for the prevention of coronavirus disease 2019 (COVID-19).

For the complete prescribing information and information available for patients/caregivers, please consult the COVISHIELD 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 www.covishield-canada.ca, or by contacting Verity Pharmaceuticals Inc. at 1-800-977-9778. Contact the company for a copy of any references, attachments or enclosures.

COVID-19 vaccines and treatments portal – COVISHIELD

Janssen COVID-19 Vaccine: Authorization with terms and conditions

Health Canada has authorized with terms and conditions, under the Interim Order, Janssen COVID-19 Vaccine, SARS-CoV-2 Vaccine [Ad26.COV2.S, recombinant], suspension for intramuscular injection, multiple dose vial (contains 5 doses of 0.5 mL) for use in relation to COVID-19.

Janssen COVID-19 Vaccine is indicated for active immunization for the prevention of coronavirus disease-2019 (COVID-19) caused by SARS-CoV-2 virus in individuals 18 years of age and older.

For the complete prescribing information and information available for patients/caregivers, please consult the Janssen 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 www.vaxcheck.jnj, or by contacting Janssen Inc. at 1-800-567-3331. Contact the company for a copy of any references, attachments or enclosures.

COVID-19 vaccines and treatments portal – Janssen COVID-19 Vaccine

Pfizer-BioNTech COVID-19 Vaccine: Update

The Pfizer-BioNTech COVID-19 Vaccine product monograph has been updated to reflect alternative and more flexible storage and/or transportation conditions of the frozen vials and transportation conditions of the thawed undiluted vials. The updated product monograph is available on the Drug Product Database or the government's covid-vaccine.canada.ca website or at pfizer.ca and CVDvaccine.ca.

Health Professional Risk Communication – Pfizer-BioNTech 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 February 2021 by Health Canada.

Acetaminophen Advisory	Health Canada advised Canadians to take precautions to prevent the unintentional exposure of young children to adult acetaminophen easy-to-swallow tablets following multiple incident reports to poison control centres. These tablets are red and sweet tasting, may seem like candy to young children, and can be packaged in bottles with a red, gear-shaped cap that is designed for easy opening and may seem like a toy.
Ceftriaxone-containing products Summary Safety Review	This safety review evaluated the risk of encephalopathy associated with ceftriaxone-containing products. Health Canada's review of the available information concluded that there may be a link. Health Canada will work with the manufacturers of ceftriaxone-containing products to update the Canadian product monographs to include the risk of encephalopathy.
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.
COVID-19 Vaccine Moderna Health Professional Risk Communication	The COVID-19 Vaccine Moderna product monograph has been updated with post-market adverse reaction information identified during pharmacovigilance activities. Anaphylaxis has been reported following COVID-19 Vaccine Moderna administration outside of clinical trials. This new information does not change the benefit-risk profile of this product. The product monograph and global English-only vial and carton labels are also being updated with new product labelling information, including brand name change. These product labelling updates are administrative in nature.
Hand sanitizers and hard surface disinfectants sold by Protegel Quebec Inc. and Hangel Canada Inc. Advisory	Health Canada warned Canadians that Protegel Quebec Inc. and Hangel Canada Inc. were selling unauthorized hand sanitizer and hard surface disinfectant products online. Unauthorized products may contain unknown ingredients and may be harmful if used. In addition, some of these unauthorized products were tested by Health Canada and found to contain less than the required ethanol to be an effective sanitizer. Other products had an eight-digit Natural Product Number belonging to a different product, while other products falsely claimed to prevent COVID-19 (see table in the advisory for details).

Perfect Sports Core Series Pure Creatine Advisory	Health Canada suspended the product licence of Perfect Sports Core Series Pure Creatine (also known as Creatine Powder) (NPN 80012948) as a result of vitamin D contamination of Lot 2006CRTN807 and because of non-compliance with Good Manufacturing Practices. The product label is also missing the statement "for adult use only". Health Canada has directed the company to recall all remaining lots from the market. In addition, Health Canada has suspended the company's site licence.
Pfizer-BioNTech COVID-19 Vaccine Health Professional Risk Communication	The Pfizer-BioNTech COVID-19 Vaccine product monograph and vial and carton labels were updated to reflect an increase in the number of doses that can be extracted from each vial, from 5 doses per vial to 6 doses. It is possible to extract a 6th dose of 0.3 mL of the diluted vaccine using low dead-volume syringes and/or needles. Excess vaccine from multiple vials should not be pooled to create extra doses. The product monograph has also been updated with post-market adverse reaction information identified during pharmacovigilance activities. Severe allergic reactions, including anaphylaxis, have been reported during mass vaccination outside of clinical trials. This new information does not change the benefit-risk profile of this product.
Ranitidine Information Update	Pharmascience Inc. recalled additional lots of its ranitidine drugs (150 mg strength tablet) after tests found N-nitrosodimethylamine (NDMA), a nitrosamine impurity, above accepted levels. A table with detailed information on the recalled lots is provided in the information update.
Tecentriq (atezolizumab) Summary Safety Review	This safety review evaluated the risk of autoimmune hemolytic anemia associated with Tecentriq. Health Canada's review of the available information concluded that there may be a link. Health Canada is working with the manufacturer to update the Canadian product monograph for Tecentriq to include the risk of autoimmune hemolytic anemia.
Unauthorized health products Unauthorized injectables and other health products from Galena Pharm Inc. pharmacy Unauthorized products (Part 1) Unauthorized products (Part 2)	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.

REVIEW ARTICLE

Certain sulfonamide diuretics and the risk of choroidal effusion with acute myopia and/or acute angle-closure glaucoma

Health Canada reviewed the potential risk of choroidal effusion, acute myopia and acute angle-closure glaucoma with the use of diuretics, including acetazolamide, after a related review was conducted by the European Medicines Agency's Pharmacovigilance Risk Assessment Committee (PRAC).[1]

Health Canada's review, which examined information related to all diuretics marketed in Canada, concluded that there is a risk of developing choroidal effusion with acute myopia and/or acute angle-closure glaucoma with the use of the following 5 diuretics: acetazolamide, chlorthalidone, hydrochlorothiazide, indapamide and metolazone*. All 5 diuretics are sulfonamide drugs.

Health Canada reviewed 49 case reports of ocular disorders in patients receiving diuretics (including one Canadian report). Some of these cases were assessed as having a possible or probable association between the diuretic and the risk of choroidal effusion and/or acute myopia and/or acute angle-closure glaucoma. The exact mechanism by which these diuretics can cause choroidal effusion, acute myopia or acute angle-closure glaucoma is unknown and therefore, it is considered an idiosyncratic reaction. This reaction has also been hypothesized in the scientific literature to be related to the drug's sulfonamide moiety.[2]

The risk of choroidal effusion with acute myopia and/or acute angle-closure glaucoma is not reflected consistently in the Canadian product monographs (CPM) for products containing acetazolamide, chlorthalidone, hydrochlorothiazide, indapamide and metolazone. Health Canada will work with manufacturers to update those CPMs.

Key messages for healthcare professionals

- There is a risk of developing choroidal effusion with acute myopia and/or acute angle-closure glaucoma with the use of certain diuretics, namely acetazolamide, chlorthalidone, hydrochlorothiazide, indapamide and metolazone.
- Symptoms of these ocular disorders include acute onset of decreased visual acuity, blurred vision or ocular pain. Symptoms typically occur within hours to weeks of drug initiation.
- Patients should be advised to seek medical treatment if they experience symptoms affecting their vision. For patients presenting with these symptoms, the diuretic treatment should be discontinued as rapidly as possible. Patients should obtain appropriate medical evaluation immediately and treatment of elevated intraocular pressure should be considered.
- Healthcare professionals are encouraged to report to Health Canada any case of choroidal effusion, acute myopia or acute angle-closure glaucoma suspected to be associated with the use of diuretics. This information will support ongoing monitoring of this safety issue.

References

1. Pharmacovigilance Risk Assessment Committee (PRAC). *Thiazide, thiazide-like diuretics and combinations – Choroidal effusion. PRAC recommendations on signals, Adopted at the 9-12 March 2020 PRAC meeting.* Amsterdam (The Netherlands): European Medicines Agency, 2020. (accessed 2021 Jan 11)
2. Krieg PH, Schipper I. Drug-induced ciliary body oedema: A new theory. Eye (Lond) 1996;10 (Pt 1):121-6.

* At the time of Health Canada's review, no information was found to support a link between metolazone and the risks of choroidal effusion with acute myopia and/or acute angle-closure glaucoma. However, based on pharmaceutical class considerations, these risks could not be excluded.

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

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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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