Health Canada Santé Canada

Canada

Health Product InfoWatch

September 2024

Contents

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.

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.

Announcement

Reminder: How to report an adverse reaction to cannabis

Health Canada's ability to monitor health and safety issues with cannabis products for medical and non-medical purposes depends, in part, on healthcare professionals, consumers and licence holders reporting adverse reactions. Healthcare professionals and consumers are encouraged to report any adverse reactions associated with cannabis, regardless of its use, to Health Canada. Under the *Cannabis Regulations*, licence holders who sell or distribute a cannabis product must report all serious adverse reactions to Health Canada.

About 40% of adverse reaction reports involving cannabis as a suspected substance were reported by healthcare professionals. These reports help Health Canada to:

- identify previously unrecognized, rare or serious side effects or problems with cannabis products
- identify potential risks of cannabis products to the health and safety of Canadians
- contribute to international data about risks of cannabis products available for sale in Canada
- communicate new and emerging risks of cannabis products to industry, hospitals, healthcare professionals and consumers in a timely manner
- undertake regulatory actions, such as changing the product label or removing the cannabis product from the Canadian market, to mitigate any identified risk to Canadians.

Adverse reaction reporting for cannabis products

To assist Health Canada in conducting thorough assessments of adverse reactions, reports should include as much of the following information as possible:

- product information (brand name, licence holder, amount of THC and/or CBD and other ingredients such as other cannabinoids, terpenes or carrier oils; lot or batch number); place and date of purchase
- details of use, including the amount used, frequency and duration of product use (including start and stop date(s) and route(s) of administration)
- other suspect products (if any)
- concomitant health products or other substances
- patient's medical history, including whether the patient was cannabis naïve or not, whether they previously consumed the suspected cannabis product and any previous known hypersensitivities or allergies to cannabis or other substances/health products
- description of the adverse reaction, including date of onset and duration
- seriousness of the adverse reaction and reason for seriousness
- any dechallenge/rechallenge information
- outcome

Adverse reactions to cannabis should be reported to Health Canada even if certain information is unknown or missing and regardless of how the cannabis was obtained. This is particularly important for adverse reactions involving vulnerable populations, including children or the elderly, as well as for adverse reactions of interest, including suspected vaping-associated lung illness or cannabis-drug interactions.

Health Canada would like to thank everyone who has been involved in reporting adverse reactions associated with cannabis in Canada. Your reports have provided Health Canada with important information that supports ongoing safety monitoring of cannabis products.

For inquiries related to this communication or information on adverse reaction reporting for cannabis, contact cannabis_oss-cannabis_bss@hc-sc.gc.ca.

Helpful links on cannabis

- Information for healthcare professionals: Cannabis (marihuana, marijuana) and the cannabinoids
- Information on cannabis adverse reaction reporting: Cannabis adverse reaction reporting guide
- Legal cannabis retailers: Authorized cannabis retailers in the provinces and territories
- Licence holders: Licensed cultivators, processors and sellers of cannabis

MONTHLY RECAP OF HEALTH PRODUCT SAFETY INFORMATION

The following is a list of health product advisories, type I drug recalls and summaries of completed safety reviews published in August 2024 by Health Canada.

ACH-Sitagliptin

Certain lots of ACH-Sitagliptin (25 mg, 50 mg and 100 mg) were recalled because they may exceed the established acceptable intake limit for the nitrosamine impurity 7-nitroso-3-(trifluoromethyl)- 5,6,7,8-tetrahydro[1,2,4] triazolo-[4,3-a]pyrazine (NTTP).

Type 1 drug recall: ACH-Sitagliptin

Breast implants

This safety review evaluated the risk of breast implant illness (BII) representative symptoms and diseases in people with breast implants. Health Canada's review of the available information found that BII representative symptoms and diseases have been reported in individuals with all types of breast implants, regardless of implant size, shape, fill, or surface texture. The extent to which this risk may be related to breast implants is currently unclear. To support informed decision-making, information on BII representative symptoms and diseases has been published on the breast implant website. Health Canada will continue to monitor this potential risk.

Summary Safety Review: Breast implants

Epinephrine Injection USP, 1 mg/10 mL single-use syringes

Given the shortage of Epinephrine Injection USP, 1 mg/10 mL single-use syringes in Canada, and to maintain continuity of supply, Health Canada has authorized the exceptional, temporary importation and sale of US-authorized Epinephrine Injection USP, 1 mg/10 mL single-dose pre-filled syringes with English-only labels by Amphastar Pharmaceuticals, Inc. There are differences in the route of administration and the delivery system between the products, which are important to note, particularly in emergency situations where epinephrine injections are commonly used.

Health Product Risk Communication: Epinephrine Injection USP, 1 mg/10 mL single-use syringes

Health First Ashwagandha Supreme capsules

Health First Network recalled one lot of Health First Ashwagandha Supreme bottles containing 120 capsules because the label shows a “Dairy Free” icon, but the product came into contact with dairy during production. This may pose serious health risks to people with a severe dairy allergy.

Advisory: Health First Ashwagandha Supreme capsules
Type 1 drug recall: Health First Ashwagandha Supreme capsules

JAMP Digoxin

JAMP Pharma Corporation recalled certain lots of JAMP Digoxin 0.0625 mg and 0.125 mg tablets as some bottles may contain tablets that weigh more or less than they should, while looking like normal-sized tablets. Patients taking an overweight or underweight tablet could unexpectedly receive a higher or lower dose than intended.

Advisory: JAMP Digoxin
Type 1 drug recall: JAMP Digoxin

JAMP-Mycophenolate

JAMP Pharma Corporation recalled all lots of JAMP-Mycophenolate 250 mg capsules as some capsules may weigh more or less than they should. Patients taking an overweight or underweight capsule could unexpectedly receive a higher or lower dose than intended.

Advisory: JAMP-Mycophenolate

Type 1 drug recall: JAMP-Mycophenolate

Ratio-Ectosone (TEVA-Ectosone) 0.1% regular lotion and 0.05% mild lotion

Teva Canada Ltd. expanded its recall to all lots of ratio-Ectosone (TEVA-Ectosone) 0.1% regular lotion and ratio-Ectosone (TEVA-Ectosone) 0.05% mild lotion after testing detected the impurity, betamethasone enol aldehyde, above the accepted limit in some additional lots. In addition, the products have been recalled because of labelling errors, including dosing instructions.

Advisory: Ratio-Ectosone (TEVA-Ectosone) 0.1% regular lotion and 0.05% mild lotion
Type 1 drug recall: Ratio-Ectosone (TEVA-Ectosone) 0.1% regular lotion and 0.05% mild lotion

Sensorcaine with Epinephrine (bupivacaine hydrochloride, 5 mg/mL and epinephrine (epinephrine bitartrate), 5 mcg/mL)

Given the critical shortage of Sensorcaine with Epinephrine (bupivacaine hydrochloride, 5 mg/mL and epinephrine (epinephrine bitartrate), 5 mcg/mL), and to maintain continuity of supply in Canada, Health Canada has authorized the exceptional, temporary importation and sale of Danish-authorized Marcain-Adrenalin (bupivacaine hydrochloride, 5 mg/mL and adrenaline (adrenaline tartrate), 5 mcg/mL) with Danish-only labels by Aspen Pharmacare Canada Inc. Healthcare professionals should be aware that there are

important differences in product labelling between the Danish-authorized product and the Canadian-authorized product.

Health Product Risk Communication: Sensorcaine with Epinephrine (bupivacaine hydrochloride, 5 mg/mL and epinephrine (epinephrine bitartrate), 5 mcg/mL)

Sodium-glucose cotransporter-2 (SGLT2) inhibitors (canagliflozin, dapagliflozin, empagliflozin)

This safety review evaluated the risks of prolonged or incident diabetic ketoacidosis (DKA), despite stopping treatment, in adult patients with type 2 diabetes with the use of sodium-glucose cotransporter-2 (SGLT2) inhibitors (canagliflozin, dapagliflozin, empagliflozin). Health Canada's review of the available information could not rule out a possible drug class effect for the risk of prolonged DKA despite stopping SGLT2 inhibitor treatment as part of standard management in adult patients with type 2 diabetes. The review also identified a number of cases of incident DKA following surgery in adult patients with type 2 diabetes taking SGLT2 inhibitors where treatment was temporarily stopped 2 days or less before surgery. Health Canada is working with the manufacturers to update and align the Canadian product monograph for SGLT2 inhibitors to include a warning about this risk, and a recommendation for temporary treatment cessation before a surgical procedure.

Summary Safety Review: Sodium-glucose cotransporter-2 (SGLT2) inhibitors (canagliflozin, dapagliflozin, empagliflozin)

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.

Advisory: Poppers
Advisory: Unauthorized sexual enhancement products
Advisory: Unauthorized skin lightening and skin treatment products
Advisory: Unauthorized treatments provided by individual posing as a practitioner at MedSkin Laser Center in Sherwood Park, Alberta
Advisory: Unauthorized UMARY Hyaluronic Acid Dietary Supplement

NEW HEALTH PRODUCT SAFETY INFORMATION

The following topic has been selected to raise awareness and encourage reporting of adverse reactions.

Product monograph update

The following safety labelling update, which was recently made to the Canadian product monographs, has been included 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.

Mounjaro (tirzepatide)

The *Warnings and Precautions*, *Adverse Reactions*, and *Patient Medication Information* sections of the Canadian product monograph for Mounjaro have been updated with the risk of **malnutrition**.

Key messages for healthcare professionals:[1]

- Malnutrition has been reported in patients receiving Mounjaro, including severe, serious and fatal events.
- Nutritional guidance and supplementation should be considered for patients receiving Mounjaro.
- Discontinuation should be considered for severe or persistent cases of malnutrition.

Reference

1. *Mounjaro (tirzepatide)* [product monograph]. Toronto (ON): Eli Lilly Canada Inc.; 2024.

Helpful links

- 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 Portal
- Drug Shortages Canada
- Medical device shortages
- COVID-19 vaccines and treatments portal

Contact us

Your comments are important to us. Let us know what you think by reaching us at: infowatch-infovigilance@hc-sc.gc.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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