Health Canada Santé Canada

Canada

Health Product InfoWatch

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REPORTING ADVERSE REACTIONS
Canada Vigilance Program
Online: Adverse Reaction and Medical Device Problem Reporting
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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.

Contents

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 March 2026 by Health Canada.

Bicillin L-A

Further to Health Canada's communication issued on February 18, 2026, additional supply of the Portuguese-authorized Lentocilin S 1200; 1 200 000 IU / 4 mL has been made available to mitigate the ongoing shortage of Canadian-authorized Bicillin L-A 1 200 000 IU / 2 mL. The new supply is available with bilingual labels.

Health Product Risk Communication: Bicillin L-A

Glucagon-like peptide 1 receptor agonists (GLP-1 RAs)

This safety review evaluated the increased risk of pulmonary aspiration in patients undergoing procedures requiring general anesthesia or deep sedation and taking GLP-1 RAs (dulaglutide-, liraglutide-, lixisenatide-, semaglutide- and tirzepatide-containing products). Health Canada's review found a possible link. Health Canada has worked with the manufacturers to update the safety information in the Canadian product monographs (CPMs) for all GLP-1 RAs to include this risk. Health Canada is also working with the manufacturers of newly approved products in the GLP-1 RA drug class to update their respective CPMs.

Summary Safety Review: Glucagon-like peptide 1 receptor agonists (GLP-1 RAs)

Ixchiq (chikungunya vaccine, live, attenuated)

Post-marketing data suggest that individuals 65 years of age and older who are medically frail with multiple chronic medical conditions may be at an increased risk of serious and life-threatening adverse reactions following recent vaccination with Ixchiq. The Canadian product monograph for Ixchiq has been updated to reflect this safety information.

Health Product Risk Communication: Ixchiq (chikungunya vaccine, live, attenuated)

Rylaze (crisantaspase)

This safety review evaluated the risk of hepatic sinusoidal obstruction syndrome associated with Rylaze (crisantaspase). Health Canada's review found a possible link. Health Canada will work with the manufacturer to update the safety information in the Canadian product monograph for Rylaze to include this risk.

Summary Safety Review: Rylaze (crisantaspase)

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: Unauthorized and counterfeit health products seized at Thumbs Up 4 Shiatsu in Mississauga

Type I recall: Nitrous Oxide Charger (2026-03-12)

Type I recall: Nitrous Oxide Charger (2026-03-19)

Vasopressin Injection, USP

There is a shortage of Vasopressin Injection, USP, 20 units/ mL (for intramuscular [IM] or subcutaneous [SC] administration) in Canada. Given the medical need, Health Canada has permitted the exceptional, temporary importation and sale of a similar but not identical product, US-authorized Vasopressin Injection, USP, 20 units/mL (for intravenous [IV] infusion) with English-only labels by Fresenius Kabi USA, LLC. The US-authorized Vasopressin Injection, USP (for IV infusion) differs significantly from the Canadian-authorized Vasopressin Injection, USP (for IM or SC administration) in indication, route of administration, packaging and formulation, dilution requirements, storage conditions and in-use periods and safety information.

Health Product Risk Communication: Vasopressin Injection, USP

Vitamin B6-containing health products

This safety review evaluated the risk of peripheral neuropathy with vitamin B6-containing health products (natural health products and prescription drugs), with a daily dose of 10 mg vitamin B6 or higher. Health Canada's review found a possible link between vitamin B6-containing natural health products and the risk of peripheral neuropathy when taken at daily doses of 10 mg vitamin B6 or higher. The review did not find sufficient evidence to establish a link with vitamin B6-containing prescription drugs. Health Canada will update the monograph for vitamin B6-containing natural health products to include this risk.

Summary Safety Review: Vitamin B6-containing health products

NEW HEALTH PRODUCT SAFETY INFORMATION

The following topics have been selected to raise awareness and encourage reporting of adverse reactions.

Safety brief

Falsely elevated digoxin levels with the chemiluminescent microparticle immunoassay test method in patients receiving enzalutamide treatment

The Architect *i*Digoxin assay is a chemiluminescent microparticle immunoassay (CMIA) used for the quantitative measurement of digoxin concentrations in human serum or plasma.

Digoxin is used in the treatment of mild-to-moderate heart failure as well as chronic atrial fibrillation.[1] The measurement of digoxin concentrations is used to inform treatment decisions and monitor for digoxin toxicity, a known risk of digoxin therapy.

Health Canada is aware of reports of falsely elevated digoxin levels with the CMIA test method in patients receiving enzalutamide, a treatment used for advanced prostate cancer, regardless of active digoxin treatment.[2,3,4] Falsely elevated levels of digoxin may lead to unnecessary discontinuation or dose decrease of digoxin, or initiation of therapy for digoxin toxicity.

Health Canada continues to monitor this risk and encourages healthcare providers and laboratories to report any problems or complications associated with the results of the Architect *i*Digoxin assay.

Key messages for healthcare professionals:

- Be aware of the potential for falsely elevated digoxin levels with the CMIA test method in patients receiving enzalutamide treatment.[2,5]
- Digoxin levels obtained through the CMIA method should be carefully assessed with appropriate caution when assessing patients receiving enzalutamide treatment.
- In the case of doubtful results, it is recommended to confirm digoxin concentration using an alternative method with no known analytical interference from enzalutamide prior to making any treatment decisions.[3]
- At this time, the Architect *i*Digoxin assay is the only known assay in Canada impacted by this analytical interference.

References

1. *PMS-Digoxin (digoxin tablets)* [product monograph]. Montréal (QC): Pharmascience Inc.; 2022.
2. Lammoza N, Hormiz M, Chiang C, Stead C, Ayhan M, Hume SC. Measurement of digoxin levels falsely affected by enzalutamide. *Med J Aust.* 2024 May 20;220(9):455-456. doi:10.5694/mja2.52289
3. Kalra D, Tesfazghi M. Falsely Elevated Digoxin Levels in Patients on Enzalutamide. *Circ Heart Fail.* 2020; 13(7):e007008. doi:10.1161/CIRCHEARTFAILURE.120.007008
4. Deguigne M, Brunet M, Abbara C, Turcant A, Le Roux G, Lelièvre B. Enzalutamide and analytical interferences in digoxin assays. *Clin Toxicol (Phila).* 2018;56(11):1150-1154. doi:10.1080/15563650.2018.1469758
5. *Xtandi (enzalutamide)* [product monograph]. Markham (ON): Astellas Pharma Canada, Inc.; 2026.

Product monograph update

The following safety labelling update, which was recently made to the Canadian product monograph, 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.

Taro-Melphalan (melphalan injection)

The *Dosage and Administration* section of the Canadian product monograph for Taro-Melphalan* has been updated to include a **change in reconstitution instructions**.

Key messages for healthcare professionals:[1]

- Prior to reconstitution, ensure that both the lyophilized powder and the supplied solvent-diluent are at room temperature (approximately 25°C).
- **Warming the diluent in the hand may aid in reconstitution.**
- Using a sterile syringe and a 20-gauge or larger needle, rapidly transfer 10 mL of the supplied solvent-diluent into the vial containing the lyophilized powder as a single quantity.
- Immediately shake the vial vigorously for at least 50 seconds until a clear solution, free of visible particles, is obtained.
- Each vial must be reconstituted individually following this procedure.

** Only the product monograph for the Taro brand of melphalan has been updated. This change was initiated by Taro Pharmaceuticals Inc. after receiving complaints regarding the reconstitution of their product.*

Reference

1. *Taro-Melphalan (melphalan injection*) [product monograph]. Brampton (ON): Taro Pharmaceuticals Inc.; 2026.

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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