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
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.

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 April 2026 by Health Canada.

Alecensaro (alectinib)

Hypertriglyceridemia, including severe and life-threatening events, has been identified as an adverse reaction associated with Alecensaro. Severe hypertriglyceridemia is considered a medical emergency, as it may lead to acute pancreatitis. The Canadian product monograph for Alecensaro will be updated to include this safety information.

Health Product Risk Communication: Alecensaro (alectinib)

Diosmin- and diosmin and hesperidin-containing natural health products

This safety review evaluated the increased risk of bleeding associated with the use of either diosmin or diosmin in combination with hesperidin. Health Canada's safety review found a possible link. Evidence suggests that the severity of bleeding may be greater in individuals who are taking medications that affect blood clotting, such as anticoagulants. Health Canada will update related monographs to include a recommendation for consumers to consult a healthcare professional prior to taking the product if they are taking medications, including anticoagulants.

Summary Safety Review: Diosmin- and diosmin and hesperidin-containing natural health products

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 injectable peptide drugs

Type I recall: Nitrous Oxide Chargers (2026-04-14)

Type I recall: Nitrous Oxide Chargers (2026-04-15)

NEW HEALTH PRODUCT SAFETY INFORMATION

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

Safety brief

Diosmin or diosmin in combination with hesperidin and the increased risk of bleeding

Diosmin and hesperidin are bioflavonoids (a diverse group of phytochemicals) that are present in a number of plants, including citrus fruits.[1,2] Natural health products (NHPs) containing diosmin and hesperidin are authorized in Canada to be used for their antioxidant effects, and for the relief of symptoms of venous insufficiency, varicose veins and hemorrhoids.

Recently, Health Canada completed a review of the potential increased risk of bleeding with the use of diosmin or diosmin in combination with hesperidin. This review was triggered by the following Canadian case reported to Health Canada.

Case report

An elderly individual started taking Hemovel, a diosmin-containing NHP, for hemorrhoids. After taking the product for 2 days at the recommended dosage, the patient developed a severe rectal hemorrhage and went to the emergency department. The treating physician suspected a possible drug interaction as the cause of bleeding. Besides taking Hemovel, it was also reported that the patient was taking Eliquis (apixaban), Entresto (sacubitril / valsartan), rosuvastatin, furosemide and amiodarone. The patient declined further investigation into the cause of the bleeding event, and their condition improved shortly after stopping Hemovel. Despite a positive dechallenge and possible temporal correlation, the hemorrhage was not reported to be medically validated and lacked laboratory evidence. Therefore, Health Canada could not further assess this case to confirm that Hemovel was the cause of the bleeding.

Other case reports of bleeding events suspected of being associated with the use of diosmin- or diosmin and hesperidin-containing NHPs were identified from the literature as well as the Canada Vigilance and World Health Organization (WHO) adverse reaction databases.

Evidence from scientific literature (*in vitro* and animal studies) suggests that either diosmin or diosmin in combination with hesperidin may interfere with certain medications, including anticoagulant and antiplatelet medications through pharmacokinetic interactions and inhibition of platelet activation and aggregation, potentially increasing bleeding risk.[3-10]

Based on the evidence reviewed, Health Canada found a possible link between the use of either diosmin or diosmin in combination with hesperidin and the increased risk of bleeding. Health Canada will update the related monographs[*,†] to include the recommendation for consumers to consult a healthcare professional prior to product use if they are taking medications, including blood thinners.

Healthcare professionals should be aware of the potential increased risk of bleeding with the use of diosmin- or diosmin and hesperidin-containing NHPs, especially in patients taking anticoagulant or antiplatelet medications.

Healthcare professionals are encouraged to report to Health Canada any suspected cases of bleeding linked to these NHPs through the Canada Vigilance Program.

** In the case of NHPs, a monograph is specific to an individual ingredient or a combination of ingredients that are authorized for use in NHPs sold in Canada. Monographs for NHP ingredients can be accessed through the Compendium of monographs.*

† The medicinal ingredient hesperidin is represented in the antioxidants monograph. Since diosmin and hesperidin are both sub-ingredients of citrus bioflavonoids, they are also captured by the citrus bioflavonoids monograph.

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Notice of market authorization with conditions

A Notice of Compliance with Conditions (NOC/c) is a form of market authorization with conditions granted to a product on the basis of promising evidence of clinical effectiveness following review of the submission by Health Canada. Communicating a NOC/c is intended to raise awareness on the details of the drug and the type of authorization granted.

Healthcare professionals are encouraged to report to Health Canada any adverse reactions suspected of being associated with marketed health products, including drugs authorized under the NOC/c policy.

The content of these notices reflects current information at the time of publication. Conditions associated with the NOC/c will remain until they have been fulfilled and authorized by Health Canada. For the most up-to-date information, consult Health Canada's NOC database.

Lunsumio (mosunetuzumab for injection) and Lunsumio SC (mosunetuzumab injection): Authorization with conditions

Health Canada has issued a Notice of Compliance, under the NOC/c policy, for Lunsumio (mosunetuzumab for injection), concentrate for solution for intravenous infusion, 1 mg/1 mL and 30 mg/30 mL, and Lunsumio SC (mosunetuzumab injection), solution for subcutaneous injection, 5 mg/0.5 mL and 45 mg/1 mL. Lunsumio/Lunsumio SC is indicated as monotherapy for the treatment of adult patients with relapsed or refractory follicular lymphoma (Grades 1 – 3a) who have received at least two prior lines of systemic therapy. Patients should be advised of the conditional market authorization for this indication.

For the complete prescribing information and information available for patients/caregivers, please consult the Lunsumio/Lunsumio SC Canadian product monograph. The product monograph can be accessed through Health Canada's Drug Product Database, the Hoffmann-La Roche Limited website or by contacting Hoffmann-La Roche Limited at 1-888-762-4388. Contact the company for a copy of any references, attachments or enclosures.

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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