



Health Product InfoWatch

October 2026

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

SUBSCRIBE

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	2
Cabergoline-containing products	
Insulin pens and cartridges manufactured by Sanofi-Aventis Canada Inc.	
Novo-Gesic Forte 500 mg (acetaminophen)	
Sarclisa (isatuximab)	
Surgical mesh used for hernia repair	
Tzield (teplizumab)	
Unauthorized health products	
ANNOUNCEMENT	3
<i>#MedSafetyWeek 2026</i>	
NEW HEALTH PRODUCT SAFETY INFORMATION	4
<i>Notice of market authorization with conditions</i>	
Hernexeos (zongertinib): Authorization with conditions	
Helpful links	5
Contact us	5
Copyright	5

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 September 2026 by Health Canada.

Cabergoline-containing products

This safety review evaluated the risk of serious hypertension, myocardial infarction, stroke and seizure in postpartum women associated with the use of cabergoline-containing products. Health Canada's review found a possible link. Health Canada will work with the manufacturers to update the product safety information in the Canadian product monograph for all cabergoline-containing products to include these risks.

[Summary Safety Review: Cabergoline-containing products](#)

Insulin pens and cartridges manufactured by Sanofi-Aventis Canada Inc.

Sanofi-Aventis Canada Inc. recalled certain units of insulin pens and cartridges from multiple lots as they may have been frozen during shipping. Insulin products that have been frozen may have reduced effectiveness. Only a limited number of units in each lot are being recalled.

[Advisory: Insulin pens and cartridges manufactured by Sanofi-Aventis Canada Inc.](#)

Novo-Gesic Forte 500 mg (acetaminophen)

Teva Canada Limited recalled 1 lot of the non-prescription drug Novo-Gesic Forte 500 mg (acetaminophen) due to the potential presence of phenolic resin or epoxy which, if ingested, may cause injury to the digestive system. The affected product was supplied to pharmacies in 1 000-count bottles and was dispensed to patients in smaller quantities.

[Advisory: Novo-Gesic Forte 500 mg \(acetaminophen\)](#)

Sarclisa (isatuximab)

Nine units from the affected lot of Sarclisa single-use vials were recalled from 3 locations in Nova Scotia as they may have been frozen during shipping.

[Type I drug recall: Sarclisa \(isatuximab\)](#)

Surgical mesh used for hernia repair

Since 2009, Health Canada has completed several safety reviews on postsurgical complications associated with surgical mesh used for hernia repair. Ongoing patient reports of postsurgical complications prompted an updated safety review. Results of the current review align with previous findings, global reports and literature. Surgical mesh for hernia repair reduces recurrence, and its overall complication rate remains comparable to non-mesh repairs. The overall benefits of using surgical mesh for hernia repair continue to outweigh the risks. Health Canada will continue to monitor the safety of surgical mesh devices.

[Summary Safety Review: Surgical mesh used for hernia repair](#)

Tziel (teplizumab)

Serious and life-threatening cases of viral reactivation, including Epstein-Barr virus and cytomegalovirus, have been reported with Tziel. Tziel is now contraindicated in patients with an active viral infection, any active

serious infection, or who are immunocompromised. The Canadian product monograph for Tzielid has been updated to include this safety information.

[Health Product Risk Communication: Tzielid \(teplizumab\)](#)

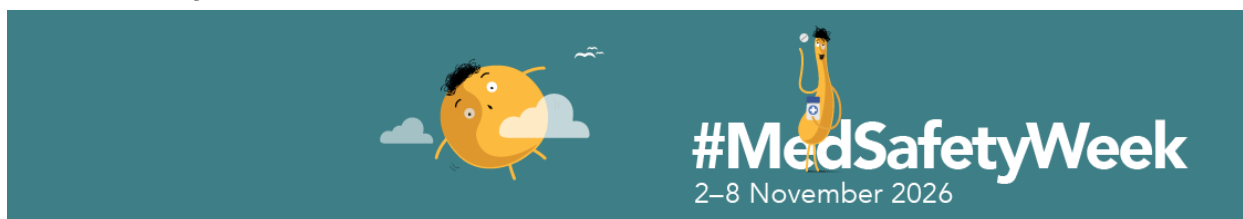
Unauthorized health products

Health Canada advised Canadians about unauthorized health products being sold at retail locations across Canada or online that may pose serious health risks.

[Advisory: Counterfeit Soprano laser hair removal and therapy devices](#)

ANNOUNCEMENT

#MedSafetyWeek 2026



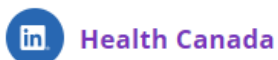
Health Canada is joining the World Health Organization's annual [#MedSafetyWeek](#) social media campaign to raise awareness about the importance of reporting adverse reactions (ARs) to health products. The 2026 campaign will take place from November 2 to 8 with the theme "Side effects – don't ignore them, report them".

Adverse reactions contribute significantly to global morbidity and mortality. While health products undergo rigorous assessment before being authorized for sale, they are typically studied in a limited number of carefully selected individuals and for a relatively short period of time. Health product safety knowledge evolves over time. Some safety issues may only become evident after a product is used by a broader population, for a longer duration of time and/or in real-world settings.

Healthcare professionals play a vital role in identifying and reporting ARs. Reporting suspected ARs to Health Canada's [Canada Vigilance Program](#) helps strengthen the Department's [post-market surveillance activities](#) and supports the ongoing assessment of health product safety. These reports provide valuable information that helps ensure the benefits of health products continue to outweigh their risks.

Health Canada also contributes to global drug safety monitoring efforts by sharing information collected through AR reports with international partners, including the World Health Organization's Programme for International Drug Monitoring, the US Food and Drug Administration and the European Medicines Agency.

To learn more about the #MedSafetyWeek campaign, follow Health Canada's social media channels starting November 2, 2026:



NEW HEALTH PRODUCT SAFETY INFORMATION

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

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](#).

Hernexeos (zongertinib): Authorization with conditions

Health Canada has issued a Notice of Compliance, under the NOC/c policy, for Hernexeos (zongertinib), 60 mg oral tablets. Hernexeos is indicated for the treatment of adult patients with unresectable or metastatic non-small cell lung cancer whose tumours have HER2 (ERBB2) tyrosine kinase domain activating mutations and who have received prior 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 Hernexeos Canadian product monograph. The product monograph can be accessed through Health Canada's [Drug Product Database](#), the [Boehringer Ingelheim \(Canada\) Ltd. website](#) or by contacting Boehringer Ingelheim (Canada) Ltd. at 1-800-263-5103, extension 84633. 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

Health Product InfoWatch Editorial Team
Marketed Health Products Directorate, Health Canada
Address Locator 1906C
Ottawa, ON K1A 0K9

Copyright

© 2026 His Majesty the King in Right of Canada. This publication may be reproduced without permission provided the source is fully acknowledged. The use of this publication for advertising purposes is prohibited. Health Canada does not assume liability for the accuracy or authenticity of the information submitted in case reports.

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.

ISSN: 2368-8025
Cat.: H167-1E-PDF
Pub.: 260000