Health Canada Santé Canada

Canada

Health Product InfoWatch

August 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

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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 July 2026 by Health Canada.

Ashwagandha for oral use

This safety review evaluated the risk of hepatotoxicity associated with the oral use of ashwagandha-containing natural health products. Health Canada's review did not find sufficient evidence to establish a definite link. However, a possible link could not be ruled out. Health Canada will continue to monitor this risk.

Summary Safety Review: Ashwagandha for oral use

Omnitrope (somatropin for injection)

Sandoz Canada Inc. recalled two lots of Omnitrope 5 mg/1.5 mL somatropin after receiving complaints of cracked and leaking glass cartridges. Cracked and leaking cartridges may lead to contamination and infection, and to lower doses than intended.

Advisory: Omnitrope (somatropin for injection)

Tavneos (avacopan)

Health Canada is reviewing significant concerns regarding the data integrity of the pivotal ADVOCATE trial, which served as the primary efficacy study supporting the authorization of Tavneos. These concerns have raised questions about the efficacy of Tavneos. Healthcare professionals are advised to NOT initiate treatment with Tavneos in new patients and to contact and monitor patients currently receiving Tavneos and assess whether continued treatment remains appropriate.

Health Product Risk Communication: Tavneos (avacopan)

NEW HEALTH PRODUCT SAFETY INFORMATION

The following topics have 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 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.

Tecfidera (dimethyl fumarate)

The *Warnings and Precautions, Adverse Reactions (Post-Market Adverse Reactions),* and *Patient Medication Information* sections of the Canadian product monograph for Tecfidera have been updated with the risk of **gastrointestinal events of perforation, ulceration, hemorrhage, and obstruction**.

Key messages for healthcare professionals:[1]

- Serious cases (some with fatal outcomes) of gastrointestinal hemorrhage, obstruction, ulcer, and ulcer associated perforation and hemorrhage have been observed in the post-marketing setting in patients taking dimethyl fumarate, with or without concomitant aspirin use.
- Monitor patients, promptly evaluate, and discontinue dimethyl fumarate for new or worsening severe gastrointestinal signs and symptoms.

Reference

1. *Tecfidera* (*dimethyl fumarate*) [product monograph]. Toronto (ON): Biogen Canada Inc., 2026.

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 an 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.

Ojemda (tovorafenib): Authorization with conditions

Health Canada has issued a Notice of Compliance, under the NOC/c policy, for Ojemda (tovorafenib), 100 mg oral tablets and 300 mg per bottle oral suspension (25 mg/mL after reconstitution). Ojemda is indicated as monotherapy for the treatment of patients 6 months of age and older with relapsed or refractory pediatric low-grade glioma harbouring a *BRAF* fusion or rearrangement, or *BRAF* V600 mutation, who have received one or more prior systemic therapies. Patients or caregivers 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 Ojemda Canadian product monograph. The product monograph can be accessed through Health Canada's Drug Product Database, the Ipsen Biopharmaceuticals Canada Inc. website or by contacting Ipsen Biopharmaceuticals Canada Inc. at 1-855-215-2288. 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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