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
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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 January 2026 by Health Canada.

Teva Octreotide for injectable suspension

Teva Canada Limited has recalled affected lots of all strengths of the prescription drug Octreotide as a precautionary measure due to deficiencies in Good Manufacturing Practices identified at its foreign manufacturing site. The deficiencies identified could lead to potential quality issues with the products, including microbiological contamination (leading to compromised sterility), contamination with foreign particles and concerns related to dosing accuracy.

Advisory: Teva Octreotide for injectable suspension
Type I drug recall: Teva Octreotide for injectable suspension

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: Fake Cialis and Viagra seized from Bitco Distribution in Ontario
Advisory: Unauthorized and counterfeit versions of glucagon-like peptide-1 (GLP-1) receptor agonist drugs such as Ozempic or Mounjaro

Announcements

Consultation: Notice of intent to control zuranolone under the Controlled Drugs and Substances Act

Health Canada has issued a Notice of Intent to add zuranolone (the active ingredient in Zurzuvae, indicated for the treatment of moderate or severe postpartum depression in adults following childbirth) to Schedule IV of the *Controlled Drugs and Substances Act* (CDSA). This is because zuranolone, a positive allosteric modulator of gamma-aminobutyric acid type A ($GABA_A$) receptor, shows potential for both misuse and physical dependence.

If finalized, zuranolone would still be prescription-only, but would come with additional oversight under the CDSA to minimize risks to public health and safety. Health Canada is encouraging all interested parties, including healthcare professionals, to review the Notice of Intent and share their views before regulatory amendments are finalized. The consultation will be open until April 18, 2026.

New clinical resource on cannabis for medical purposes

Health Canada recently published a new resource providing information on the use of cannabis for medical purposes. The content applies to legal cannabis products produced and sold in Canada.

This publication offers evidence-based information to support patients in making informed decisions about using cannabis for medical purposes and to assist healthcare professionals in discussing cannabis for medical purposes with their patients.

This document includes these topics:

- General information on cannabis for medical purposes including potential drug interactions and situations when cannabis should not be used.
- Choosing a cannabis product with guidance on product composition and how to read product labels to help with the choice of product.
- Using a cannabis product including methods of administration, instructions for use, dosing considerations, storage, and monitoring.
- Side effects outlining both short- and long-term effects of cannabis use and how to report side effects.

For inquiries related to this communication, contact the Controlled Substances and Cannabis Branch at cannabis@hc-sc.gc.ca.

NEW HEALTH PRODUCT SAFETY INFORMATION

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

Product monograph updates

The following safety labelling updates, which were recently made to the Canadian product monographs, have 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.

Absorica LD, Accutane and Epuris (isotretinoin)

The *Warnings and Precautions* and *Patient Medication Information* sections of the Canadian product monographs for Absorica LD, Accutane and Epuris have been updated with the risk of **sacroiliitis**.

Key messages for healthcare professionals:[1,2,3]

- Sacroiliitis has been reported in patients exposed to isotretinoin.
- To differentiate sacroiliitis from other causes of back pain, in patients with clinical signs of sacroiliitis, further evaluation may be needed including imaging modalities such as MRI.
- In cases reported post-marketing, sacroiliitis improved after discontinuation of isotretinoin and appropriate treatment.

References

1. *Absorica LD* (*isotretinoin*) [product monograph]. Brampton (ON): Sun Pharma Canada Inc.; 2025.
2. *Accutane* (*isotretinoin*) [product monograph]. Binningen (Switzerland): CHEPLAPHARM Schweiz GmbH; 2025.
3. *Epuris* (*isotretinoin*) [product monograph]. Mississauga (ON): Cipher Pharmaceuticals Inc.; 2025.

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.

Hyrnuo (sevabertinib): Authorization with conditions

Health Canada has issued a Notice of Compliance, under the NOC/c policy, for Hyrnuo (sevabertinib), 10 mg oral tablets. Hyrnuo is indicated for the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer whose tumours have *HER2* (*ERBB2*) tyrosine kinase domain activating mutations and who have received a 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 Hyrnuo Canadian product monograph. The product monograph can be accessed through Health Canada's Drug Product Database, the Bayer Inc. website or by contacting Bayer Inc. at 1-800-265-7382. Contact the company for a copy of any references, attachments or enclosures.

Ziihera (zanidatamab for injection): Authorization with conditions

Health Canada has issued a Notice of Compliance, under the NOC/c policy, for Ziihera (zanidatamab for injection), powder for solution for intravenous infusion, 300 mg/vial. Ziihera is indicated for the treatment of adults with previously treated, unresectable locally advanced or metastatic HER2-positive (IHC 3+) biliary tract cancer, as monotherapy. 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 Ziihera Canadian product monograph. The product monograph can be accessed through Health Canada's Drug Product Database, the Jazz Pharmaceuticals Canada Inc. website or by contacting Jazz Pharmaceuticals Canada Inc. at 1-800-520-5568. Contact the company for a copy of any references, attachments or enclosures.

Medication error alert

This section is intended to inform healthcare professionals and support patient safety by highlighting reports of medication errors.

Psyllium and the risk of choking

Psyllium is a soluble fibre widely used to treat constipation. There are many natural health products containing psyllium available for sale in Canada. An ISMP Canada Safety Bulletin highlights the importance of understanding the instructions for use and warnings associated with these products. When used outside of recommended guidelines, serious harm may result, including fatalities as described in the bulletin.

Healthcare professionals are reminded that psyllium should be mixed with an adequate volume of liquid and administered immediately at the point of care. Mixing psyllium with thickened liquids or food, such as applesauce, may lead to adverse outcomes for patients (e.g., choking). Psyllium is contraindicated in individuals experiencing dysphagia.

Information for patients about the volume of liquid to mix with psyllium and other safety tips can be found in the consumer newsletter at MedError.ca.

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

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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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