Health Canada Santé Canada

Canada

Health Product InfoWatch

September 2025

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 August 2025 by Health Canada.

Copaxone (glatiramer acetate) and other glatiramer acetate products

Although uncommon, glatiramer acetate can cause anaphylactic reactions, which may be fatal and can occur at any time during treatment, from as early as after the first dose, or even months, up to years, after initiation of treatment. Symptoms of anaphylactic reactions may be similar to and may overlap with those of common immediate post-injection reactions. However, anaphylactic reactions generally appear within one hour of glatiramer acetate administration and are typically more severe, worsen over time and require treatment. The Canadian product monograph (CPM) for Copaxone has been updated to include this information and Health Canada is working with the manufacturers of other glatiramer acetate products to update their respective CPMs.

Health Product Risk Communication: Copaxone (glatiramer acetate)

Advisory: Glatiramer acetate

Crysvita (burosumab)

Crysvita (burosumab) may increase the risk of severe hypercalcemia in patients with underlying tertiary hyperparathyroidism and other risk factors, such as prolonged immobilization, dehydration, hypervitaminosis D, or renal impairment. The Canadian product monograph for Crysvita has been updated to include this information.

Health Product Risk Communication: Crysvita (burosumab)

Prescription opioids

This safety review evaluated the risk of esophageal dysfunction with long-term use of prescription opioids (buprenorphine, butorphanol, codeine, diamorphine, fentanyl, hydrocodone, hydromorphone, meperidine, methadone, morphine, nalbuphine, normethadone, oxycodone, tapentadol and tramadol). Health Canada's review found a possible link. Health Canada will work with the manufacturers to update the Canadian product monographs for prescription opioids to include this risk.

Summary Safety Review: Prescription opioids

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 (counterfeit) Cialis and Viagra seized from Toronto, Pickering, and Brantford stores

Advisory: Unauthorized injectable peptide drugs seized and sold by Canada Peptide

Advisory: Unlicensed Mitolux UV sunlamps for Vitamin D

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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