



Health Product InfoWatch

June 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
Finasteride and dutasteride	
Givlaari (givosiran)	
Tramadol-containing products	
Unauthorized health products	
Announcement	3
Breast implant recall subscription service	
NEW HEALTH PRODUCT SAFETY INFORMATION	3
Health product safety summary	3
2025 AR data	
Safety brief	6
Vitamin B6 health products and peripheral neuropathy	
Helpful links	7
Contact us	7
Copyright	7

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 May 2026 by Health Canada.

Finasteride and dutasteride

This safety review evaluated the risk of sexual dysfunction associated with the use of finasteride-containing products and dutasteride-containing products, to identify and assess newly emerging safety information, and to determine whether current risk minimization measures remain appropriate. Health Canada's review, which builds on the evidence that existed at the time of market authorization of finasteride and dutasteride, provides a larger body of evidence on the link between the use of these products and the risk of sexual dysfunction. Health Canada will work with the manufacturers to enhance the product safety information in the Canadian product monograph for all finasteride-containing products and dutasteride-containing products to include a warning about the risk of sexual dysfunction.

[Summary Safety Review: Finasteride and dutasteride](#)

Givlaari (givosiran)

This safety review evaluated the risk of acute pancreatitis associated with the use of Givlaari. Health Canada's review found a possible link. Health Canada will work with the manufacturer to update the Canadian product monograph to include the risk of acute pancreatitis.

[Summary Safety Review: Givlaari \(givosiran\)](#)

Tramadol-containing products

This safety review evaluated the risk of prolonged, persistent or recurrent hiccups associated with the use of tramadol-containing products. Health Canada's review found a possible link. Health Canada will work with the manufacturers to update the Canadian product monograph of all tramadol-containing products to include the risk of prolonged, persistent or recurrent hiccups.

[Summary Safety Review: Tramadol-containing 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.

[Type I recall: GHK-Cu & BPC-157 powder \(unauthorized active pharmaceutical ingredients\)](#)

[Type I recall: Nitrous Oxide Chargers](#)

Announcement

Breast implant recall subscription service

Health Canada has launched a new way for patients, healthcare professionals, and others [to register to receive direct alerts](#) about breast implant recalls and safety issues. This new subscription complements Health Canada's existing [broader email subscription service](#) for breast implants, which includes other safety information in addition to recall alerts.

Given that healthcare of people with breast implants continues to be of interest to many Canadians, a [printable poster](#) is available for health professionals to display in their offices to help inform patients about this service. Learn more about [breast implants](#).

NEW HEALTH PRODUCT SAFETY INFORMATION

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



Health product safety summary

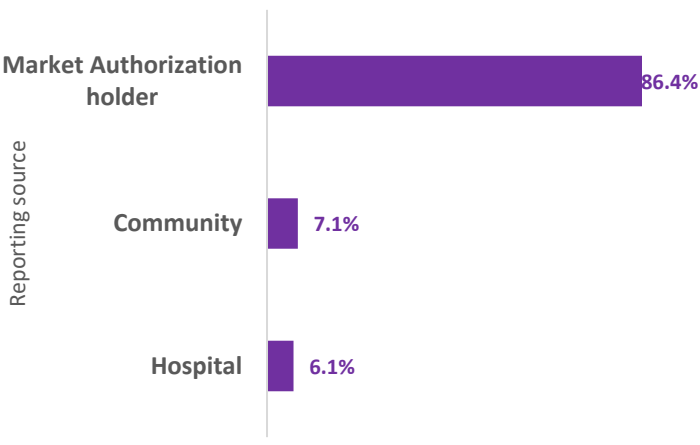
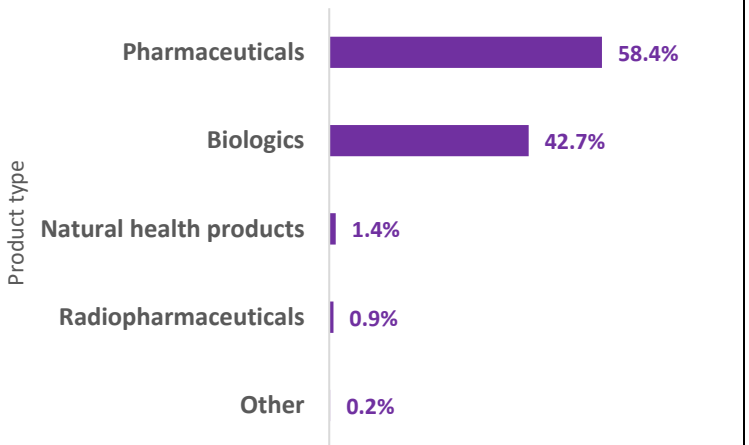
Post-market reporting systems help in the identification and analysis of new safety information for health products so that appropriate action can be taken to minimize risks to human health. Adverse reactions (ARs) suspected of being associated with the use of health products can be [reported](#) to the [Canada Vigilance Program \(CVP\)](#) in Health Canada, who holds the responsibility of monitoring the safety of health products in Canada. Market authorization holders and hospitals are required to submit AR reports to the CVP. The CVP also receives voluntary reports from community members (consumers, patients, and non-hospital-based healthcare professionals).





This summary contains information about domestic AR cases reported for pharmaceuticals, natural health products, biologics, radiopharmaceuticals, disinfectants, and sanitizers with disinfectant claims, received by the CVP in 2025. These reports are suspected associations, which reflect the reporter's observations and opinions, and do not reflect any Health Canada assessment of association between the health product and the reaction(s).

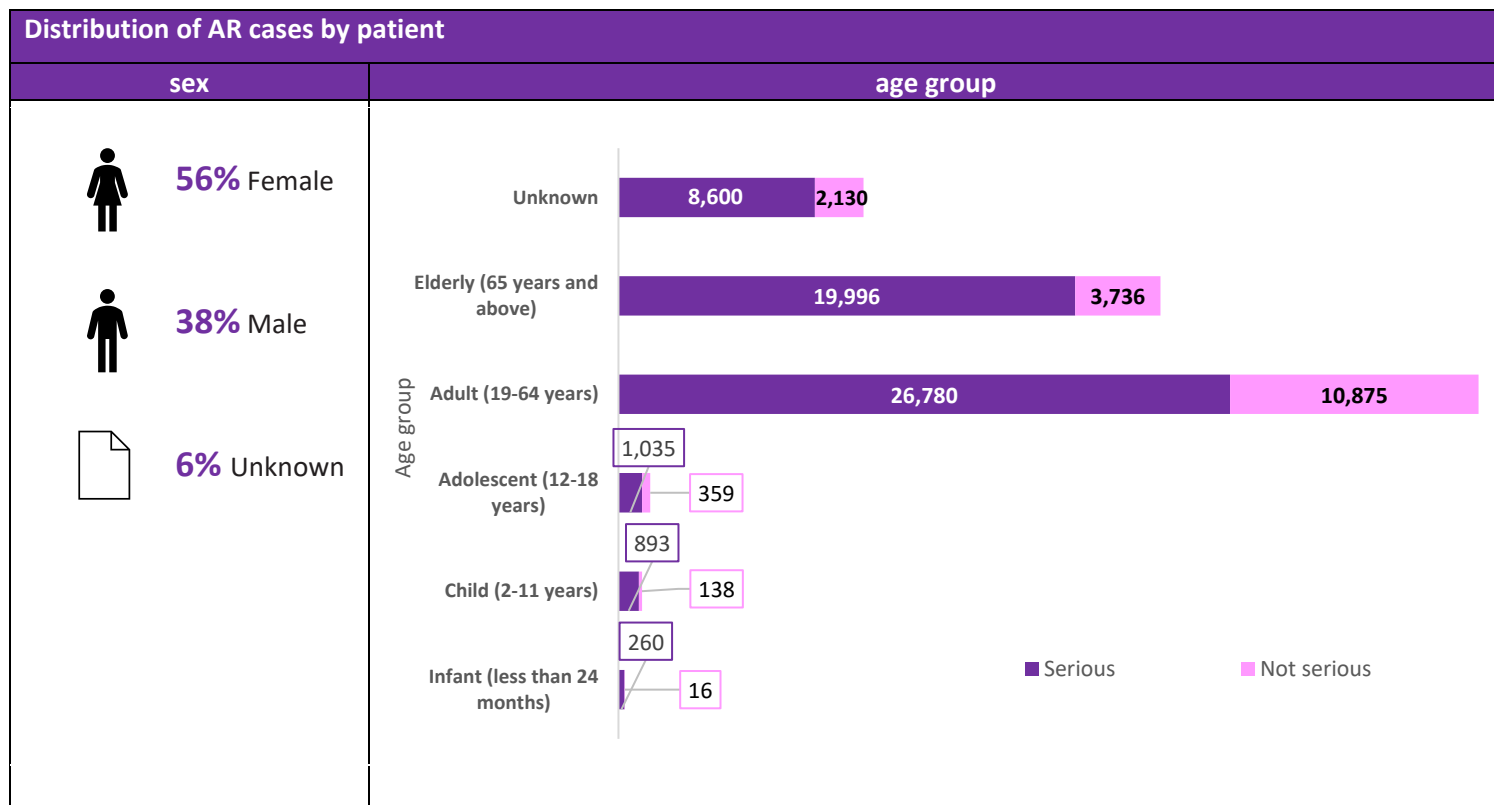
For more information, contact the [Marketed Health Products Directorate](#).

2025 AR data

<p>186,275 reports of ARs in Canada were received by the CVP from January 1 to December 31, 2025</p> <p>▼</p> <p>These reports represent 74,818 domestic AR cases*</p>	<p> 77% of cases were classified as serious.</p> <p>A case can have more than one reported reason for seriousness. Out of these serious cases:</p> <ul style="list-style-type: none"> • 33% required hospitalization • 10% reported a death • 4% were life-threatening 	<p> 14 potential safety issues were identified from AR reports for health products received during this period and for 2 of these, work is ongoing to determine if they are safety signals.</p> <p>AR reports received in 2025 also helped support the validation and assessment of safety signals from other sources (e.g., new safety information from foreign regulators and market authorization holders, and medical and scientific literature).</p>
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Distribution of AR cases by																	
reporting source	product type																
<p>Reporting source</p>  <table border="1"> <tr> <td>Market Authorization holder</td> <td>86.4%</td> </tr> <tr> <td>Community</td> <td>7.1%</td> </tr> <tr> <td>Hospital</td> <td>6.1%</td> </tr> </table>	Market Authorization holder	86.4%	Community	7.1%	Hospital	6.1%	<p>Product type</p>  <table border="1"> <tr> <td>Pharmaceuticals</td> <td>58.4%</td> </tr> <tr> <td>Biologics</td> <td>42.7%</td> </tr> <tr> <td>Natural health products</td> <td>1.4%</td> </tr> <tr> <td>Radiopharmaceuticals</td> <td>0.9%</td> </tr> <tr> <td>Other</td> <td>0.2%</td> </tr> </table>	Pharmaceuticals	58.4%	Biologics	42.7%	Natural health products	1.4%	Radiopharmaceuticals	0.9%	Other	0.2%
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Distribution of AR cases by reporter type			
<p> 16% physician</p>	<p> 8% pharmacist</p>	<p> 45% other health professional</p>	<p> 31% consumer/other</p>



Top 5 reported

suspect health product groups		ARs	
Anatomical Therapeutic Chemical (ATC) group	% of times reported	System Organ Class	% of times reported
Immunosuppressants	49%	General disorders and administration site conditions	51%
Antineoplastic agents	15%	Injury, poisoning and procedural complications	28%
Psycholeptics	4%	Infections and infestations	23%
Analgesics	4%	Gastrointestinal disorders	22%
Drugs used in diabetes	3%	Nervous system disorders	17%

* A case consists of all information describing the AR(s) experienced by one patient at one time, which is/are suspected of being related to the use of one or more health products. A case may include an initial AR report and possibly one or more follow-up reports that provide additional information. Duplicate cases may exist if an AR report about the same event was received from different reporters.



Thank you for reporting!

Note that because of updated information received by the Canada Vigilance Program, there may be differences in the number of reports and adverse events retrieved at different dates.

Safety brief

Vitamin B6 health products and peripheral neuropathy

Vitamin B6 is a naturally occurring, water-soluble vitamin, present in many commonly consumed foods and added to some supplemented/fortified foods. It is also available in health products. In Canada, vitamin B6 health products are regulated as natural health products (NHPs) or as prescription drugs. Vitamin B6 is authorized for use in NHPs to help in energy and nutrient metabolism, tissue formation, red blood cell formation, and to prevent vitamin B6 deficiency.¹ Prescription drugs containing vitamin B6 are typically used for the management of nausea and vomiting in pregnancy or for use before, during, and/or after pregnancy to support nutritional status and reduce risk of nutrient-deficiency related complications.^{2,3}

Health Canada conducted a [review](#) of available information from foreign regulatory agencies, Canadian and international adverse reaction reports, as well as the scientific literature, and found a possible association between vitamin B6-containing NHPs and the risk of peripheral neuropathy, when taken at daily doses of 10 mg or higher. Health Canada's review did not find sufficient evidence to establish an association between vitamin B6-containing prescription drugs and the risk of peripheral neuropathy, despite these products containing similar amounts of vitamin B6 to what is found in NHPs.

For vitamin B6-containing NHPs, Health Canada has updated the [Multi-Vitamin/Mineral Supplements Monograph](#) to include information on this risk. Patients taking vitamin B6-containing health products are reminded to review product labels and follow recommended dosing instructions.

Healthcare professionals are advised to:

- Counsel patients to be aware of the warning signs and symptoms of peripheral neuropathy associated with vitamin B6 supplementation, including sensory nerve problems, such as numbness, tingling, and pain in the extremities. Patients should be advised to stop use and consult a healthcare professional if symptoms occur.
- In cases of suspected vitamin B6-associated peripheral neuropathy, review all health products that the patient is taking to confirm their vitamin B6 content.*
- [Report](#) any adverse reactions suspected of being associated with vitamin B6-containing health products, including both NHPs and prescription drugs, to the [Canada Vigilance Program](#).

Health Canada will continue to monitor the safety of vitamin B6-containing health products, as it does for all health products on the Canadian market, to identify and assess potential harm. Health Canada will take appropriate and timely action should new health risks be identified.

* Be aware of supplemented sources of vitamin B6, including energy drinks, when assessing patient exposure and determining appropriate management.

References

1. Health Canada. Multi-vitamin/mineral supplements monograph. Published April 24, 2026. Accessed May 7, 2026. https://webprod.hc-sc.gc.ca/nhp/nd-bdipsn/atReq?atid=multi_vitmin_suppl2&lang=eng#a7-1
2. *Diclectin (doxylamine succinate and pyridoxine hydrochloride)* [product monograph]. Blainville (QC): Duchesnay Inc.; 2021.
3. *Pregvit and Pregvit folic 5 (vitamin-mineral supplement tablets)* [product monograph]. Blainville (QC): Duchesnay Inc.; 2024.

Helpful links

- [Recalls and Safety Alerts Database](#)
- [New Safety and Effectiveness Reviews](#)
- [Canada Vigilance Adverse Reaction Online Database](#)
- [Glossary of Fields in the 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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