



Health Product InfoWatch

June 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.

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MONTHLY RECAP OF HEALTH PRODUCT SAFETY INFORMATION

The following is a list of [health product advisories](#), [type 1 drug recalls](#) and [summaries of completed safety reviews](#) published in May 2025 by Health Canada.

Gadolinium-based contrast agents

This safety review evaluated the risk of serious adverse reactions, including seizures, encephalopathy, coma and death, with off-label intrathecal use of gadolinium-based contrast agents (Dotarem [gadoterate meglumine], Gadovist 1.0 [gadobutrol], Magnevist [gadopentetate dimeglumine], MultiHance [gadobenate dimeglumine], Omniscan [gadodiamide], Primovist [gadoxetate disodium] and ProHance [gadoteridol]) (GBCAs). Health Canada’s review found a possible link. Health Canada is working with the manufacturers to update the Canadian product monographs for all GBCAs to include the risk of serious adverse reactions, including seizures, encephalopathy, coma and death, with off-label intrathecal use.

[Summary Safety Review: Gadolinium-based contrast agents](#)

JAMP-pregabalin 50 mg

JAMP Pharma Corp. recalled one lot of JAMP-pregabalin because some manufacturer bottles labelled to contain 50 mg capsules may contain 150 mg capsules. This could lead to patients receiving a much larger dose than prescribed, which could result in an overdose and pose serious, potentially fatal health risks.

[Advisory: JAMP-pregabalin 50 mg](#)

[Type 1 drug recall: JAMP-pregabalin 50 mg](#)

Seasonique (levonorgestrel and ethinyl estradiol tablets, and ethinyl estradiol tablets)

Teva Canada Ltd. recalled one lot of Seasonique prescription birth control after receiving a complaint that a package was missing 2 pills, which may increase the risk of pregnancy.

[Advisory: Seasonique \(levonorgestrel and ethinyl estradiol tablets, and ethinyl estradiol tablets\)](#)

[Type 1 drug recall: Seasonique \(levonorgestrel and ethinyl estradiol tablets, and ethinyl estradiol tablets\)](#)

Sivem ezetimibe 10 mg

Sivem Pharmaceuticals ULC recalled one lot of Sivem ezetimibe 10 mg tablets because some bottles may also contain perindopril 4 mg tablets. Taking perindopril when prescribed ezetimibe may pose serious health risks.

[Advisory: Sivem ezetimibe 10 mg](#)

[Type 1 drug recall: Sivem ezetimibe 10 mg](#)

Stivarga (regorafenib)

This safety review evaluated the risk of thrombotic microangiopathy (TMA) associated with the use of Stivarga (regorafenib). 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 TMA.

Summary Safety Review: Stivarga (regorafenib)

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 Viagra seized from Pacific Fresh Food Market in Pickering, ON](#)

[Advisory: Fake Viagra seized from Queen St. Variety store in Toronto](#)

[Advisory: Unauthorized sexual enhancement products](#)

NEW HEALTH PRODUCT SAFETY INFORMATION

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

Health product safety summary

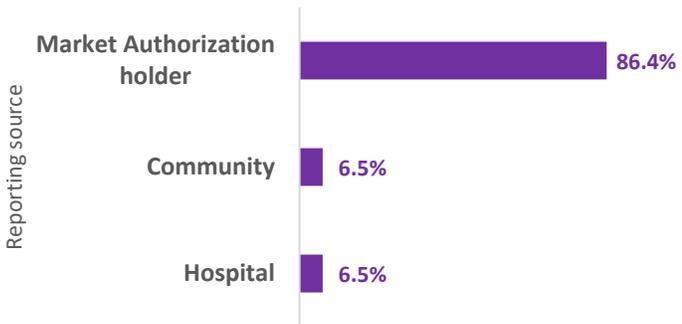
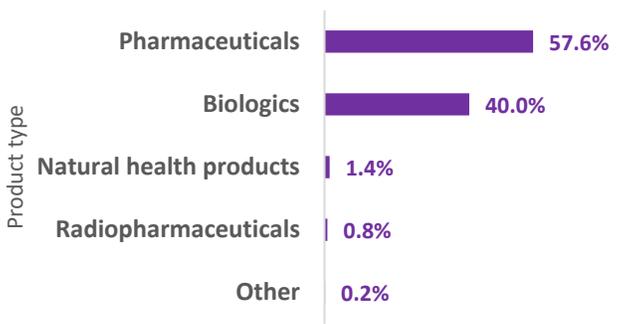
Post-market reporting systems help in the identification and analysis of new safety information for health products so that appropriate action can be taken to minimize risks to human health. Adverse reactions (ARs) suspected of being associated with the use of health products can be [reported](#) to 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 2024. These reports are suspected associations, which reflect the reporter's observations and opinions, and does not reflect any Health Canada assessment of association between the health product and the reaction(s).

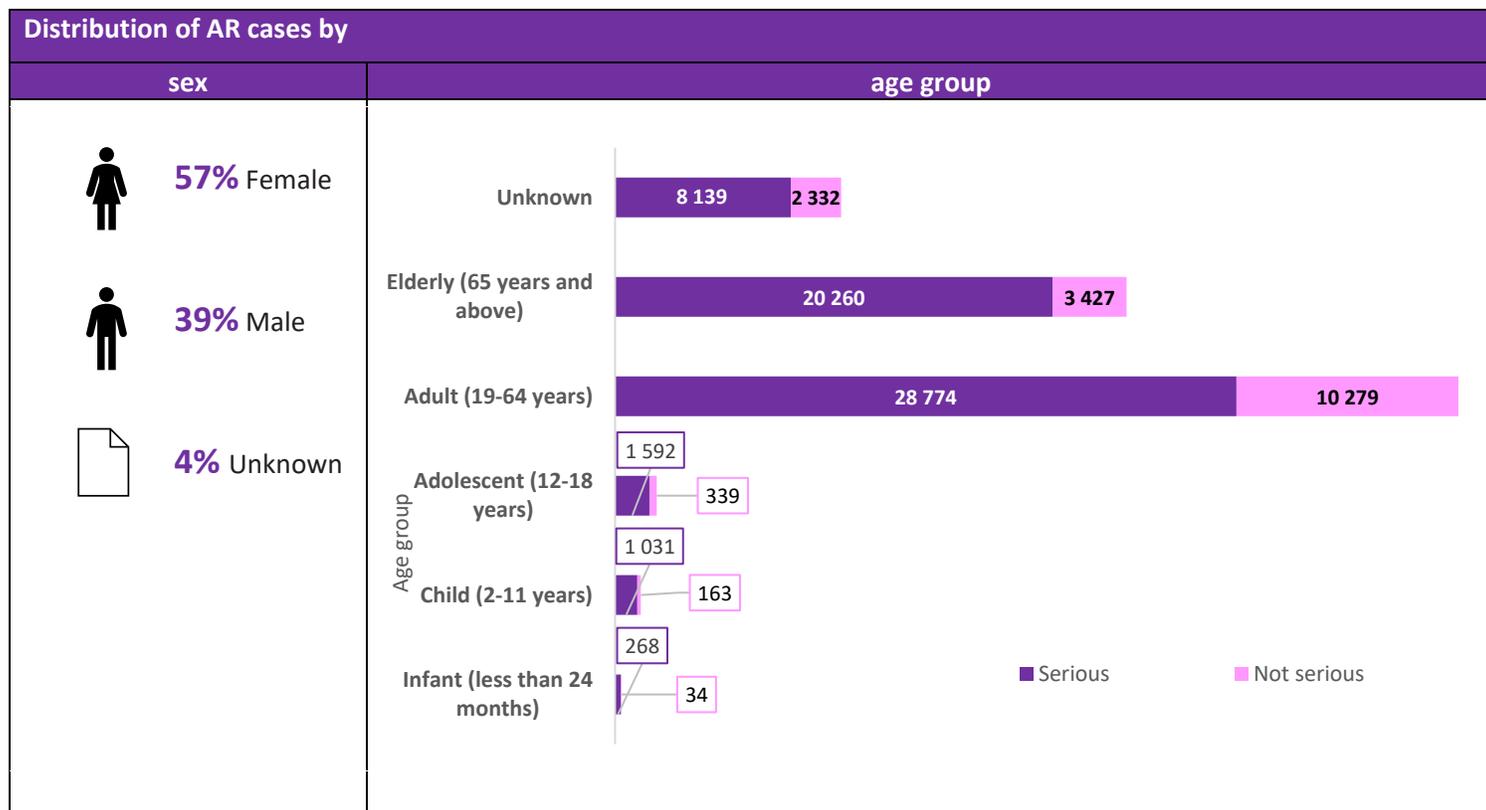
For more information, contact the [Marketed Health Products Directorate](#).

2024 AR data

<p>202,008 reports of ARs in Canada were received by the CVP from January 1 to December 31, 2024</p> <p>▼</p> <p>These reports represent 76,638 domestic AR cases*</p>	<p> 78% of cases were classified as serious</p> <ul style="list-style-type: none"> • 26% required hospitalization • 3% were life-threatening • 8% reported a death 	<p> 13 potential safety issues were identified from AR reports for health products during this period and for 2 of these, reviews are ongoing to determine if they are safety signals.</p> <p>AR reports received in 2024 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		Distribution of AR cases by 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>6.5%</td> </tr> <tr> <td>Hospital</td> <td>6.5%</td> </tr> </table>	Market Authorization holder	86.4%	Community	6.5%	Hospital	6.5%	<p>Product type</p>  <table border="1"> <tr> <td>Pharmaceuticals</td> <td>57.6%</td> </tr> <tr> <td>Biologics</td> <td>40.0%</td> </tr> <tr> <td>Natural health products</td> <td>1.4%</td> </tr> <tr> <td>Radiopharmaceuticals</td> <td>0.8%</td> </tr> <tr> <td>Other</td> <td>0.2%</td> </tr> </table>	Pharmaceuticals	57.6%	Biologics	40.0%	Natural health products	1.4%	Radiopharmaceuticals	0.8%	Other	0.2%
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Distribution of AR cases by reporter type			
<p> 18% physician</p>	<p> 7% pharmacist</p>	<p> 46% other health professional</p>	<p> 29% 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	47%	General disorders and administration site conditions	52%
Antineoplastic agents	15%	Injury, poisoning and procedural complications	30%
Drugs for obstructive airway diseases	4%	Infections and infestations	24%
Psycholeptics	4%	Gastrointestinal disorders	22%
Analgesics	4%	Nervous system disorders	16%

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

Vaccine safety summary

Health Canada and the Public Health Agency of Canada (PHAC) share the responsibility of monitoring the safety of vaccines in Canada. Market authorization holders are required to report serious adverse events following immunization (AEFIs) to the Canada Vigilance Program (CVP) in Health Canada. The CVP also receives voluntary reports from healthcare professionals and consumers. While hospitals must report serious adverse drug reactions that were documented within their facility, they do not have to report an adverse reaction to a vaccine if they have submitted an AEFI report on that case to their local public health unit. These reports are submitted by provincial and territorial public health authorities to the [Canadian Adverse Events Following Immunization Surveillance System](#) in PHAC.

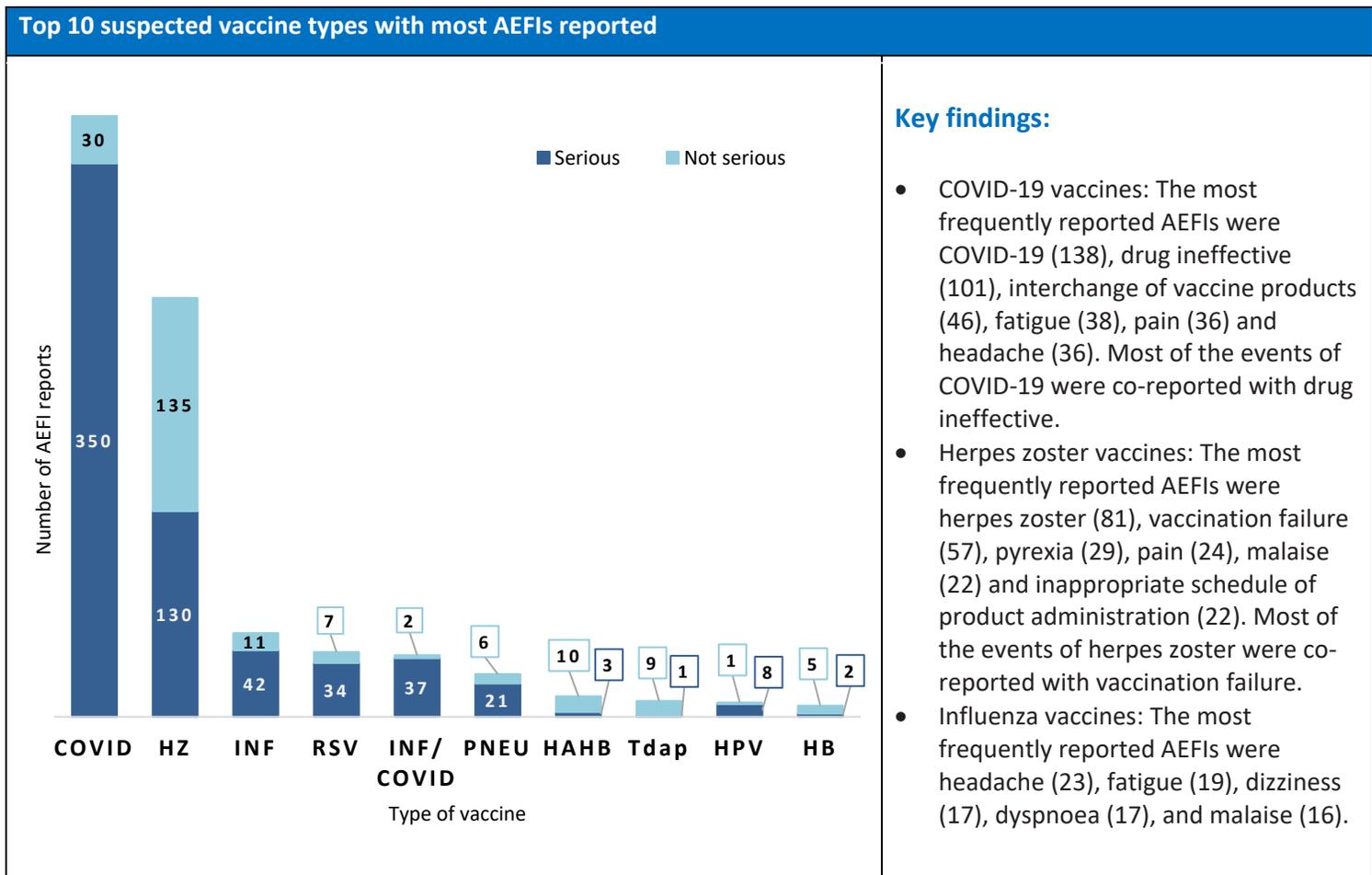
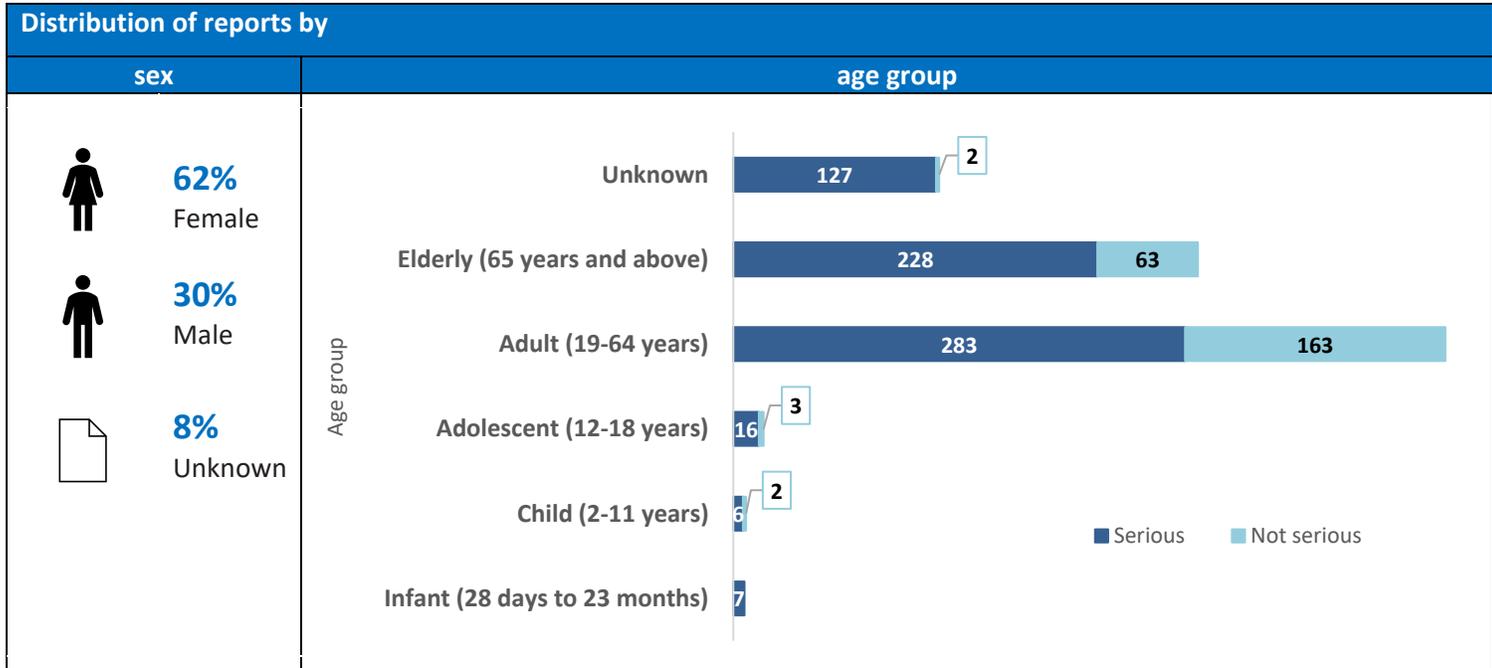
For more information, contact the [Marketed Health Products Directorate](#).

2024 AEFI data

<p>900 reports of AEFIs were received by the CVP from January 1 to December 31, 2024, for all vaccines marketed in Canada</p>	<p> 74% of reports were classified as serious</p> <hr/> <ul style="list-style-type: none"> • 14% required hospitalization • 4% were life-threatening • 3% reported a death[†] 	<p> No new safety signals (potential safety issues) for vaccines were identified by the review of the reports received during this period.[‡]</p>
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Distribution of reports by reporter type

<p> 9% physician</p>	<p> 17% pharmacist</p>	<p> 21% other health professional</p>	<p> 53% consumer/other</p>
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†The information provided in these AEFI reports was not sufficiently detailed to assess the causal association between the reported event and the vaccine.

‡Serious events that were reported were either already listed in the product monographs of the respective vaccine or deemed unlikely to be related to the vaccination based on the presence of underlying medical conditions and/or concomitant medications, which could have contributed to the events.



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.

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](#).

Amphetamines

The *Warnings and Precautions*, *Overdosage*, and *Patient Medication Information* sections of the Canadian product monographs for all amphetamines in Canada have been, or will be, updated with the risks of **QTc prolongation, Takotsubo cardiomyopathy and posterior reversible encephalopathy syndrome (PRES)**.

Key messages for healthcare professionals:¹

QTc Prolongation:

- Amphetamines have been shown to prolong the QTc interval in some patients.
- Amphetamines should be used with caution in patients with a prolonged QTc interval or congenital Long QT syndrome, those treated with drugs affecting the QTc interval, or those with relevant pre-existing cardiac disease or electrolyte disturbances.
- As a reminder, amphetamines are contraindicated in patients with symptomatic cardiovascular disease and also in patients with moderate to severe hypertension.

Overdosage:

- Takotsubo cardiomyopathy may develop with amphetamine overdose.
- PRES has been reported in association with amphetamine overdose. Symptoms indicating PRES include headache, altered mental status, seizures and visual disturbances. Diagnosis should be confirmed by radiological procedure (e.g., MRI). If PRES is suspected or diagnosed, appropriate measures should be

taken. Symptoms of PRES are usually reversible but may evolve into ischemic stroke or cerebral hemorrhage. Delay in diagnosis and treatment may lead to permanent neurological sequelae.

Reference

1. *Adderall XR (mixed salts amphetamine)* [product monograph]. Toronto (ON): Takeda Canada Inc., 2025.

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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Vaccine Type Legend

Full name of the vaccine group	Vaccine type	Serious	Not serious
COVID-19	COVID	350	30
Herpes Zoster	HZ	130	135
Influenza	INF	42	11
Respiratory syncytial virus	RSV	34	7
Influenza/COVID-19	INF/COVID	37	2
Pneumococcal	PNEU	21	6
Hepatitis A and Hepatitis B	HAHB	3	10
Tetanus, diphtheria (reduced), acellular pertussis	Tdap	1	9
Human papillomavirus	HPV	8	1
Hepatitis B	HB	2	5