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
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 December 2024 by Health Canada.

Betahistine and TEVA-Betahistine

Affected lots of Betahistine and TEVA-Betahistine tablets have been recalled as they exceeded or may have exceeded the interim acceptable intake limit for *N*-nitroso-betahistine.

Type 1 drug recall: Betahistine
Type 1 drug recall: TEVA-Betahistine

Chimeric Antigen Receptor T-cell (CAR-T) therapies - Breyanzi (lisocabtagene maraleucel), Carvykti (ciltacabtagene autoleucel), Kymriah (tisagenlecleucel), Tecartus (brexucabtagene autoleucel) and Yescarta (axicabtagene ciloleucel)

This safety review evaluated the risk of secondary T-cell malignancy associated with the use of CAR-T therapies. Health Canada's review found a possible link. Health Canada is working with the manufacturers to align the Canadian product monographs for all CAR-T therapies to include information about this risk.

Summary Safety Review: CAR-T therapies - Breyanzi (lisocabtagene maraleucel), Carvykti (ciltacabtagene autoleucel), Kymriah (tisagenlecleucel), Tecartus (brexucabtagene autoleucel) and Yescarta (axicabtagene ciloleucel)

HMG-CoA reductase inhibitors - atorvastatin, fluvastatin, lovastatin, pravastatin, rosuvastatin and simvastatin

This safety review evaluated the risk of myasthenia gravis, including ocular myasthenia, associated with the use of HMG-CoA reductase inhibitors. Health Canada's review found a possible link. Health Canada will work with the manufacturers to update the Canadian product monographs for all statin products that do not currently include this risk.

Summary Safety Review: HMG-CoA reductase inhibitors - atorvastatin, fluvastatin, lovastatin, pravastatin, rosuvastatin and simvastatin

PMS-Cinacalcet

Affected lots of PMS-Cinacalcet have been recalled as they may have exceeded the established acceptable intake limit for *N*-nitroso-cinacalcet.

Type 1 drug recall: PMS-Cinacalcet

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: Unauthorized sexual enhancement products
Advisory: Unauthorized skin lightening and skin treatment 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 2023. 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).

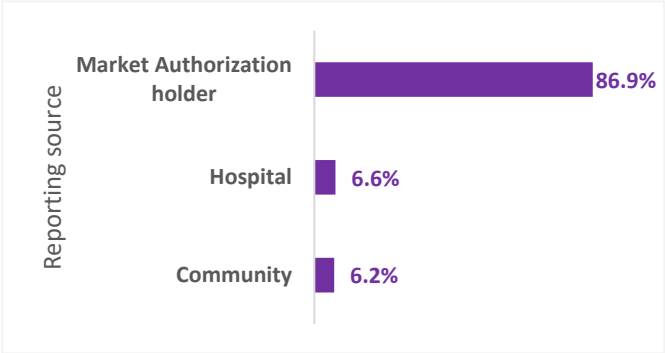
For more information, contact the Marketed Health Products Directorate.

2023 AR data

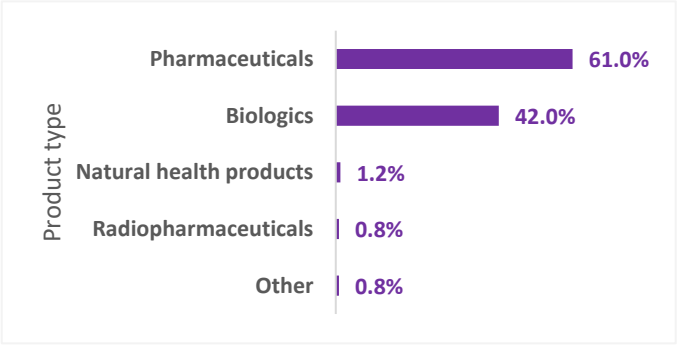
213,089 reports of ARs were received by the CVP from January 1 to December 31, 2023 ▼ These reports represent **75,515** domestic AR cases*	**74%** of cases were classified as serious • **24%** required hospitalization • **3%** were life-threatening • **9%** reported a death	**11** potential safety issues were identified from AR reports for health products during this period and **4** of these were considered safety signals. AR reports received in 2023 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).

Distribution of AR cases by

reporting source



product type



Distribution of AR cases by reporter type

22%
physician

8%
pharmacist

45%
other health professional

25%
consumer/other

Distribution of AR cases by

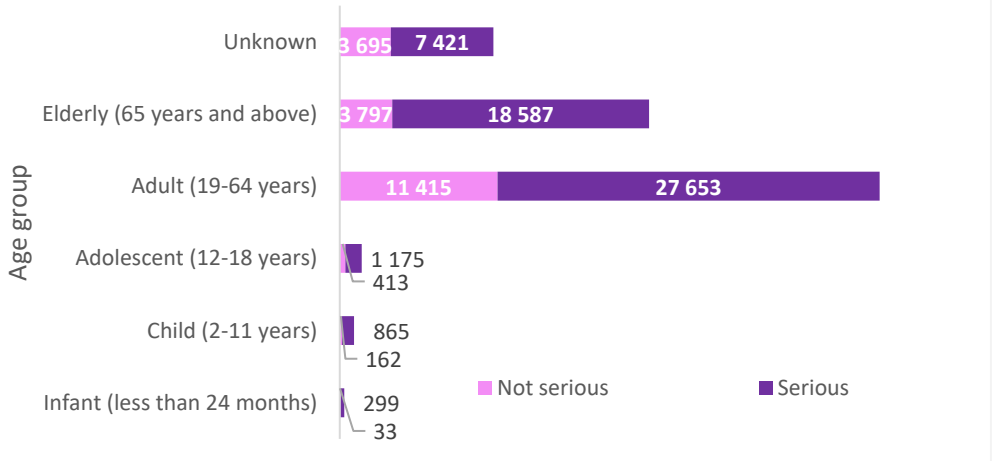
sex

58% Female

38% Male

4% Unknown

age group



Top 5 reported			
suspect health product groups		**ARs**	
Anatomical Therapeutic Chemical (ATC group)	% of times reported	System Organ Class	% of times reported
Immunosuppressants	**45%**	General disorders and administration site conditions	**57%**
Antineoplastic agents	**17%**	Injury, poisoning and procedural complications	**30%**
Psycholeptics	**5%**	Infections and infestations	**23%**
Analgesics	**3%**	Gastrointestinal disorders	**21%**
Drugs for obstructive airway diseases	**3%**	Nervous system disorders	**17%**

* 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.

2023 AEFI data

483 reports of AEFIs were received by the CVP from January 1 to December 31, 2023*	**76%** of reports were classified as serious • **13%** required hospitalization • **3%** were life-threatening • **3%** reported a death†	No new safety signals were identified for vaccines during this period.‡

Distribution of reports by reporter type

14%	19%	20%	47%
physician	pharmacist	other health professional	consumer/other

Distribution of reports by

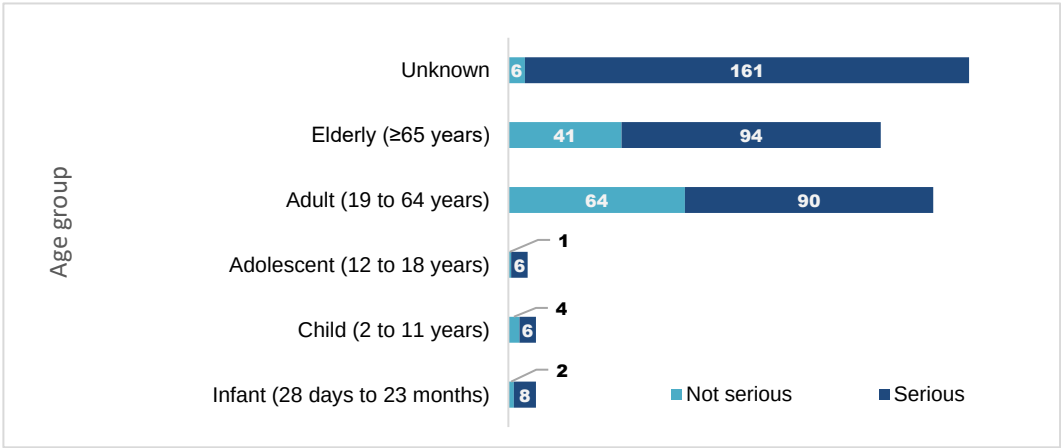
sex

63% Female

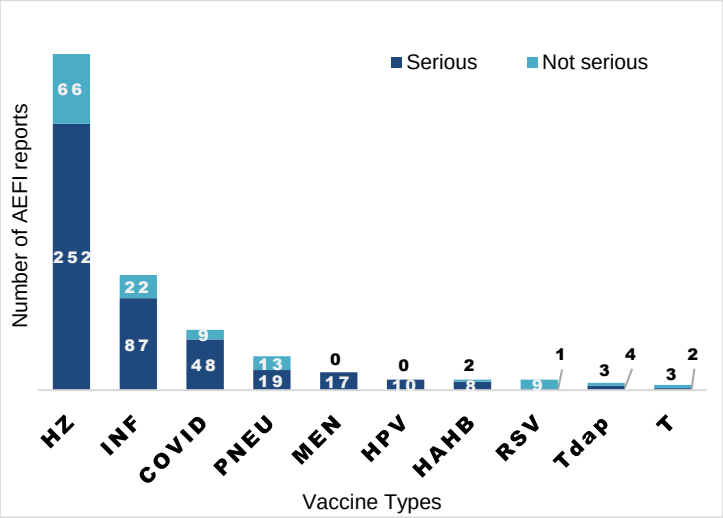
28% Male

9% Unknown

age group



Top 10 reported suspect vaccine types



The COVID data represents AEFI reports where the COVID vaccine was reported in association with another vaccine.

Key findings:

- Herpes zoster vaccines: The 5 most frequently reported AEFIs were herpes zoster, vaccination failure, pain, pyrexia and pain in extremity. Most of the events of herpes zoster were co-reported with vaccination failure.
- Influenza vaccines: The 5 most frequently reported AEFIs were dyspnoea, pain, pneumonia, fatigue, and headache.
- For all vaccines: Other commonly reported terms included vomiting, erythema and pruritus.

*These results exclude AEFI reports where a COVID-19 vaccine was the sole vaccine suspected. For information about adverse events that individuals have reported after receiving a COVID-19 vaccine as the sole suspected vaccine in

Canada in 2023, please visit the Reported side effects following COVID-19 vaccination in Canada webpage. https://health-infobase.canada.ca/covid-19/vaccine-safety/

†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.

Cannabis products adverse reaction data summary

Health Canada is responsible for monitoring the risks of cannabis products in Canada. Licence holders who sell or distribute cannabis products must report all serious adverse reactions (ARs) involving these products to Health Canada, as outlined in the *Cannabis Adverse Reaction Reporting Guide*. Consumers, patients, healthcare professionals, medical cannabis clinics and other individuals are also encouraged to voluntarily report any ARs involving cannabis.

For more information, please contact the Office of Cannabis Science and Surveillance.

2023 AR data

On January 10, 2025, Health Canada published a new report, which provides an overview of the cannabis-related ARs reported to Health Canada in 2023. This annual report is designed to help stakeholders better understand Health Canada's Vigilance Framework, which is used for cannabis products, and the AR data regarding cannabis.

As part of this release, the Key findings: Cannabis-related side effects data exploration tool was also updated. This tool presents data on key indicators of cannabis-related ARs collected by Health Canada from 2018 to 2023, allowing users to explore and interact with the data at an aggregate level.

Thank you for reporting!

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.

Contrave (naltrexone hydrochloride and bupropion hydrochloride), Wellbutrin (bupropion hydrochloride) and Zyban (bupropion hydrochloride)

The *Warnings and Precautions, Adverse Reactions (Post-Market Adverse Reactions), Dosage and Administration,* and *Patient Medication Information* sections of the Canadian product monographs for Contrave, Wellbutrin and Zyban have been updated with information on the risk of **unmasking of Brugada syndrome**.

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

- There have been isolated post-marketing reports of unmasking of Brugada syndrome with bupropion-containing products. Brugada syndrome is a disorder characterized by syncope, characteristic ECG changes, such as right bundle branch block and ST segment elevation in right precordial leads, and a risk of cardiac arrest and sudden death.
- It is advised to avoid use of bupropion-containing products in patients with Brugada syndrome. If any of these products are considered in patients with Brugada syndrome or in patients at risk of having Brugada syndrome (e.g., patients with unexplained syncope, patients with a family history of cardiac arrest or sudden death), an evaluation by a cardiologist should be sought prior to initiating treatment, to assess suitability of treatment and to determine the most appropriate strategy for monitoring cardiac effects.
- Patients should be informed about the signs and symptoms of Brugada syndrome.
- If unmasking of Brugada syndrome occurs, discontinue treatment with the bupropion-containing product.

References

1. *Contrave (naltrexone hydrochloride and bupropion hydrochloride)* [product monograph]. Laval (QC): Bausch Health, Canada Inc.; 2023.
2. *Wellbutrin (bupropion hydrochloride)* [product monograph]. Laval (QC): Bausch Health, Inc.; 2024.
3. *Zyban (bupropion hydrochloride)* [product monograph]. Laval (QC): Bausch Health, Canada Inc.; 2023.

Nolvadex-D (tamoxifen citrate)

The *Warnings and Precautions* and *Patient Medication Information* sections of the Canadian product monograph for Nolvadex-D* have been updated with the risk of **QTc interval prolongation** in patients with underlying risks for QT prolongation and cardiac comorbidities**.**

Key messages for healthcare professionals:[1]

- At the recommended dose, Nolvadex-D may prolong the QTc interval on the electrocardiogram (ECG) in patients with underlying risks for QT prolongation and cardiac comorbidities.
- ECG and electrolyte monitoring are recommended before and during treatment in such patients.

* At the time of publication, the Canadian product monograph update for Nolvadex-D has been completed. Updates for other tamoxifen citrate products will follow.

Reference

1. *Nolvadex-D (tamoxifen citrate)* [product monograph]. Mississauga (ON): AstraZeneca Canada 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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Vaccine Type Legend

Full name of the vaccine group	Vaccine type	Serious	Not serious
Herpes Zoster Vaccine	HZ	252	66
Influenza vaccine	INF	87	22
COVID-19 vaccines	COVID	48	9
Pneumococcal vaccine	PNEU	19	13
Meningococcal vaccine	MEN	17	0
Human papillomavirus vaccine	HPV	10	0
Hepatitis A, B vaccine	HAHB	8	2
Respiratory syncytial virus	RSV	1	9
Tetanus, diphtheria (reduced), acellular pertussis vaccine	TDAP	4	3
Tetanus vaccine	T	2	3

The Health Product InfoWatch thanks you for 10 years!

2015 – 2025