Health Canada Santé Canada

Canada

Health Product InfoWatch

October 2025

Contents

REPORTING ADVERSE REACTIONS

Canada Vigilance Program
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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.

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 September 2025 by Health Canada.

Acetaminophen

Health Canada maintains that there is no conclusive evidence that using acetaminophen as directed during pregnancy causes autism or other neurodevelopmental disorders. Health Canada's advice is based on robust, rigorous assessments of the available scientific evidence. Any new evidence that could affect recommendations will be carefully evaluated.

Advisory: Acetaminophen

Garcinia gummi-gutta- and hydroxycitric acid-containing natural health products

This safety review evaluated the risk of hepatotoxicity with the use of either *Garcinia gummi-gutta* or hydroxycitric acid. Health Canada's review found a possible link. Health Canada will update the monographs for *Garcinia gummi-gutta* and hydroxycitric acid to include this risk. Health Canada expects licence holders to update the risk information on product labels.

Summary Safety Review: Garcinia gummi-gutta and hydroxycitric acid-containing natural health products

Kids by Babyganics SPF 50 mineral sunscreen totally tropical

Following a recall in February 2025, Health Canada has reviewed additional testing data and confirmed that the recalled lots of Kids by Babyganics SPF 50 mineral sunscreen totally tropical do not contain the noted impurity and are safe to use. As a result, the company may resume the sale of undistributed units. Consumers can safely use the products as directed.

Advisory: Kids by Babyganics SPF 50 mineral sunscreen totally tropical

Turmeric- and curcuminoid-containing natural health products for oral use

This safety review evaluated the risk of hepatotoxicity with the oral use of either turmeric- or curcuminoid-containing natural health products. Health Canada's review found a possible link. Health Canada will update the monographs that include the medicinal ingredients turmeric and curcuminoids for oral use to include this risk. Health Canada expects licence holders to update the risk information on product labels.

Summary Safety Review: Turmeric- and curcuminoid-containing natural health products for oral use

Announcement

Distribution of the reserve list for antimicrobial drugs via the Canadian Clinical Drug Data Set

The Canadian Clinical Drug Data Set (CCDD), a drug terminology and coding system, is a free tool that facilitates the exchange of standardized drug and medical device information across diverse digital health

systems. It also provides for the classification and identification of defined groups of medications, called special groupings. As of September 2025, drug products listed in Health Canada's reserve list for antimicrobial drugs have been added as a distinct category within this special groupings file. Health Canada's Office of Submissions and Intellectual Property (OSIP), along with data scientists from the Business Facilitation and Modernization Directorate, collaborated with the Bureau of Gastroenterology, Infection and Viral Diseases on this new addition to the CCDD.

Health Canada's reserve list for antimicrobial drugs provides prescribers with guidance on agents that should be reserved for the treatment of confirmed or suspected infections from multi-drug resistant organisms. This initiative promotes the appropriate use of critical antimicrobials, preserving their effectiveness, and is a part of broader efforts to strengthen antimicrobial stewardship aligned with the Pan-Canadian Action Plan on Antimicrobial Resistance.

Given that the CCDD is integrated into multiple digital health platforms, updates to the reserve list can be automatically and seamlessly distributed across connected systems. With scheduled monthly updates, the CCDD offers a reliable and predictable source for tracking changes to products on the reserve list.

For more information about the reserve list for antimicrobial drugs, please visit: http://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/reserve-list-antimicrobial.html

For more information about the CCDD, please contact the CCDD unit in OSIP at: drug.terminology-terminologies.des.medicaments@hc-sc.gc.ca

NEW HEALTH PRODUCT SAFETY INFORMATION

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

Safety brief

Change in the colour from teal to red for the ferrule / cap of marketed cisatracurium besylate injectable products

Cisatracurium besylate is a non-depolarizing skeletal neuromuscular blocking (NMB) agent with an intermediate onset and duration of action indicated as an adjunct to general anesthesia, to facilitate non-emergency endotracheal intubation, and to provide skeletal muscle relaxation during surgery or mechanical ventilation.[1]

Medication errors involving NMB agents have the potential to result in severe harm due to the action of these drugs to paralyze muscle function essential for breathing.[2] Incidents in which patients inadvertently received NMB agents without adequate ventilatory support have resulted in serious or fatal outcomes.[3,4]

Stakeholders in Canada have advocated for strategies and system safeguards to prevent patient harm from the unsafe use of these medications.[2] In 2016, Health Canada, in collaboration with the Institute for Safe Medication Practices Canada (ISMP Canada) published the *Good Labelling and Package Practices Guide*. This

guide includes recommendations for manufacturers on the labelling and packaging of NMB agents to differentiate them from other drugs and mitigate selection errors.[5] The recommendations encourage the inclusion of a warning statement on the label, ferrule and cap of all NMB agents as follows: "Warning: Paralyzing Agent" or "Paralyzing Agent." Manufacturers are also encouraged to consider using a red ferrule and cap, with the warning printed in white lettering, or alternatively, a clear cap to allow visualization of the ferrule and its printed warning. In addition, the use of a red cap and/or ferrule with white lettering should be restricted to NMB agents only.

These labelling and packaging features have been successfully implemented, and NMB agents in Canada display warning text in either white or black print on the cap and/or ferrule. The use of the colour red has also been widely adopted for NMB agents. However, until recently, marketed cisatracurium besylate products maintained a teal coloured closure.

Figure 1. Examples of vial closures for NMB agents marketed in Canada.[2]

While several cisatracurium besylate products are authorized, including a new product from Hikma, Cisatracurium Besylate Injection, USP Multi-dose (DIN 02557665), with a red cap and ferrule (May 2025),[6] currently only one is marketed in Canada: Cisatracurium Besylate Injection, USP Multidose (DIN02408813) manufactured by Omega Laboratories Limited, which has a teal-coloured ferrule and either a clear or teal cap. A survey conducted by ISMP Canada and HealthPRO Canada in July 2024 indicated strong support among healthcare professionals for the implementation of a colour change to red for cisatracurium besylate products to align with other NMB agents on the Canadian market.[7]

The manufacturer for Omega's cisatracurium product has notified Health Canada of its intention to change the colour of the vial closure system to red. The first lot of Cisatracurium Besylate Injection, USP Multidose (DIN02408813) with a red cap and ferrule is expected to be available on the market by the end of March 2026. Healthcare professionals should be aware of a transition period during which both packaging types will be available, until the existing teal-coloured stock is depleted. During this time, Omega's Cisatracurium Besylate Injection, USP Multidose may be available in either the new packaging with a red cap and ferrule, or the current packaging with a teal-colored ferrule and a clear or teal cap.

Health Canada will continue to encourage all manufacturers marketing NMB agents in Canada to use red ferrules and red or clear caps, which are recognized as unique identifiers for NMB agents, to support the safe use of these agents.

Healthcare professionals are advised to be aware of this important change to the vial closure colour for cisatracurium besylate products and remain vigilant when selecting and administering NMB agents to patients. Healthcare professionals are advised to report medication errors involving these agents to the Canadian Medication Incident Reporting and Prevention System (CMIRPS), a program in which Health Canada participates.

References

1. *Cisatracurium Besylate Injection USP Multidose (cisatracurium besylate)* [product monograph]. Montreal (QC): Omega Laboratories Limited; 2024.
2. Institute for Safe Medication Practices Canada. Neuromuscular blocking agents: sustaining packaging improvements over time. ISMP Canada Safety Bulletin. 2014;14(7):1-7. Accessed September 16, 2025. https://ismpcanada.ca/wp-content/uploads/ISMPCSB2014-7_NeuromuscularBlockingAgents.pdf
3. Institute for Safe Medication Practices Canada. "Paralyzing" mix-ups in the operating room: opportunity to improve safety with neuromuscular blockers. ISMP Canada Safety Bulletin. 2004;4(7):1-7. Accessed September 16, 2025. https://ismpcanada.ca/wp-content/uploads/ISMPCSB2004-07.pdf
4. Vettoretti L, Berthier F, Besch G, Valnet-Rabier M-B. Medication errors related to neuromuscular blocking agents: analysis of the French National Pharmacovigilance Database. British Journal of Anaesthesia. 2025;135(1):242-244. Accessed September 16, 2025. https://www.bjanaesthesia.org/article/S0007-0912(25)00216-8/fulltext
5. Health Canada. Good Label and Package Practices Guide for Prescription Drugs. 2016. Accessed September 16, 2025. https://publications.gc.ca/collections/collection_2016/sc-hc/H164-195-1-2016-eng.pdf
6. *Cisatracurium Besylate Injection USP Multi-dose (cisatracurium besylate)* [product monograph]. Mississauga (ON): Hikma Canada Limited; 2025.
7. Institute for Safe Medication Practices Canada and HealthPRO Canada. Survey Results: August 2024. Accessed September 16, 2025. https://caccn.ca/wp-content/uploads/2024/08/ISMP-Survey-Results-Aug-2024.pdf

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.

Amtagvi (lifileucel): Authorization with conditions

Health Canada has issued a Notice of Compliance, under the NOC/c policy, for Amtagvi (lifileucel), cell suspension of 7.5 x 10^9 to 72 x 10^9 viable cells for intravenous infusion. Amtagvi is indicated for the treatment of adult patients with unresectable or metastatic melanoma that has progressed on or after at least one prior systemic therapy including a PD-1 blocking antibody, and if BRAF V600 mutation positive, a BRAF inhibitor with or without a MEK inhibitor, and who have no satisfactory alternative treatment options. 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 Amtagvi Canadian product monograph. The product monograph can be accessed through Health Canada's Drug Product Database, the Iovance Biotherapeutics, Inc. website or by contacting Iovance Biotherapeutics, Inc. at 1-833-215-7566. Contact the company for a copy of any references, attachments or enclosures.

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.

ISSN: 2368-8025
Cat.: H167-1E-PDF
Pub.: 250000