

Health Product InfoWatch

August 2025



REPORTING ADVERSE REACTIONS

Canada Vigilance Program
Online: [Adverse Reaction and Medical Device Problem Reporting](#)
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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 I drug recalls](#) and [summaries of completed safety reviews](#) published in July 2025 by Health Canada.

Epinephrine injection USP, Sodium Bicarbonate injection USP and Dextrose injection USP

Affected lots of Epinephrine injection USP, Sodium Bicarbonate injection USP and Dextrose injection USP were recalled as they may contain the presence of microbiological contamination.

[Type I drug recall: Epinephrine injection USP, Sodium Bicarbonate injection USP and Dextrose injection USP](#)

Mylan-Cinacalcet

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

[Type I drug recall: Mylan-Cinacalcet](#)

NRA-Amlodipine

One lot of NRA-Amlodipine 5 mg tablets has been recalled because some bottles may contain the wrong tablets, which have been identified as metoprolol succinate prolonged-release 12.5 mg tablets. Substituting amlodipine (5 mg) with metoprolol (12.5 mg) can lead to serious adverse reactions.

[Advisory: NRA-Amlodipine](#)

[Type I drug recall: NRA-Amlodipine](#)

PMS-Methylphenidate CR

One lot of PMS-Methylphenidate CR 10 mg capsules has been recalled as it exceeds the acceptable intake limit for *N*-nitroso-methylphenidate.

[Type I drug recall: PMS-Methylphenidate CR](#)

RIVA-Fluoxetine

Affected lots of RIVA-Fluoxetine 10 mg capsules have been recalled as they may exceed the interim acceptable intake limit for *N*-nitroso-fluoxetine.

[Type I drug recall: RIVA-Fluoxetine](#)

Taro-Doxorubicin Liposomal

One lot of Taro-Doxorubicin Liposomal has been recalled as it may contain the presence of particulate matter.

[Type I drug recall: Taro-Doxorubicin Liposomal](#)

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 Natrol DHEA Mood & Stress health product sold by Retail Revolt](#)

[Advisory: Unauthorized sexual enhancement products](#)

[Advisory: Unauthorized workout supplements](#)

NEW HEALTH PRODUCT SAFETY INFORMATION

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

Medication error alert

Brand name confusion between Diclectin and Dicetel

Diclectin and Dicetel are both authorized as prescription drugs in Canada. They are 2 distinct medications with key differences in active ingredients, indication, formulation and dosage schedule.

Diclectin is a combination of doxylamine succinate (an antihistamine) and pyridoxine hydrochloride (vitamin B6). It is indicated for the management of nausea and vomiting in pregnancy.¹ Dicetel (pinaverium bromide) is a calcium antagonist that induces relaxation of the gastrointestinal and biliary tracts. It is indicated for the treatment and relief of symptoms associated with irritable bowel syndrome and functional disorders of the biliary tract.² Both products have been on the Canadian market for over 20 years. While both products are available in a tablet form, Diclectin comes as delayed-release tablets containing 10 mg doxylamine succinate and 10 mg pyridoxine hydrochloride, whereas Dicetel is available as film-coated tablets containing 50 mg or 100 mg pinaverium bromide. Diclectin is usually taken as 1 tablet in the morning, 1 tablet mid-afternoon, and 2 tablets at bedtime while Dicetel is usually taken as 50 mg or 100 mg 3 times daily.

In 2014, the Institute for Safe Medication Practices Canada published a case of medication error caused by brand name confusion between Diclectin and Dicetel. In this case, a pregnant patient was prescribed Diclectin but was inadvertently dispensed Dicetel.³ Such medication errors continue to occur with these products due to the similarity of their brand names, despite differences in tablet strength and dosing regimens.

Health Canada recently received a domestic report involving a pregnant patient who was erroneously prescribed Dicetel 100 mg instead of Diclectin for the treatment of pregnancy-related nausea. The prescription was filled at a community pharmacy, and the patient reportedly took the incorrect medication for 2 weeks. According to the report, the patient did not experience any adverse reactions from the treatment, although the nausea remained uncontrolled. It is unknown whether the error caused harm to the fetus.

Healthcare professionals are reminded to be vigilant of the look-alike/sound-alike risk associated with the brand names of Diclectin and Dicetel. Healthcare professionals are also encouraged to report medication errors caused by brand name confusion between these two products to the [Canadian Medication Incident Reporting and Prevention System \(CMIRPS\)](#), a program in which Health Canada participates.

References

1. *Diclectin (doxylamine succinate and pyridoxine hydrochloride)* [product monograph]. Blainville (QC): Duchesnay Inc.; 2021.
2. *Dicetel (pinaverium bromide)* [product monograph]. Etobicoke (ON) BGP Pharma ULC; 2014.
3. Kawano A, Li Q (Kathy), Ho C. ISMP: Preventable Medication Errors – Look-alike/Sound-alike Drug Names. Published 2014. Accessed July 9, 2025. <https://pharmacyconnection.ca/wp-content/uploads/2021/05/pharmacy-connection-spring-2014.pdf>

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](#).

Ilaris (canakinumab)

The *Warnings and Precautions* and *Patient Medication Information* sections of the Canadian product monograph for Ilaris have been updated with the risk of **drug reaction with eosinophilia and systemic symptoms (DRESS)**.

Key messages for healthcare professionals:¹

- DRESS has rarely been reported in patients treated with Ilaris, predominantly in patients with systemic juvenile idiopathic arthritis.
- Patients with DRESS may require hospitalization, as this condition may be fatal.
- If signs and symptoms of DRESS are present and an alternative etiology cannot be established, Ilaris should not be readministered and a different treatment considered.

Reference

1. *Ilaris (canakinumab)* [product monograph]. Montreal (QC): Novartis Pharmaceuticals Canada Inc.; 2025.

Oral anticoagulants (apixaban, dabigatran, edoxaban, rivaroxaban, warfarin)

The *Warnings and Precautions*, *Adverse Reactions (Post-Market Adverse Reactions)* and *Patient Medication Information* sections of the Canadian product monographs (CPMs) for oral anticoagulants* containing apixaban, dabigatran, edoxaban, rivaroxaban and warfarin are being updated with the risk of **anticoagulant-related nephropathy**.

Key messages for healthcare professionals:¹⁻⁴

- There have been post-marketing reports of anticoagulant-related nephropathy, presenting as acute kidney injury, following the use of oral anticoagulants.
- During treatment with these drugs, close monitoring, including renal function evaluation, is advised in patients with excessive anticoagulation, compromised renal function and hematuria.

* At the time of publication, the CPMs for Eliquis, Lixiana, Pradaxa, and Xarelto have been updated. CPM updates for other oral anticoagulant products will follow.

References

1. *Eliquis (apixaban)* [product monograph]. St-Laurent (QC): Bristol-Myers Squibb Canada; 2025.
2. *Lixiana (edoxaban)* [product monograph]. Laval (QC): Servier Canada Inc.; 2024.
3. *Pradaxa (dabigatran)* [product monograph]. Burlington (ON): Boehringer Ingelheim Canada Ltd.; 2025.
4. *Xarelto (rivaroxaban)* [product monograph]. Mississauga (ON): Bayer Inc.; 2024.

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](#).

Braftovi (encorafenib): Authorization with conditions

Health Canada has issued a Notice of Compliance, under the Notice of Compliance with Conditions policy, for a new indication for Braftovi** (encorafenib), 75 mg oral capsules. The new indication for Braftovi is in combination with cetuximab and mFOLFOX6, for the treatment of patients with metastatic colorectal cancer (mCRC) with a BRAF V600E mutation, as detected by a validated test. 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 Braftovi Canadian product monograph. The product monograph can be accessed through Health Canada's [Drug Product Database](#), the [Pfizer](#) website or by contacting Pfizer at 1-800-463-6001. Contact the company for a copy of any references, attachments or enclosures.

** Braftovi's updated product monograph with this NOC/c indication is dated July 2025.

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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