Health Canada Santé Canada

Canada

Health Product InfoWatch

October 2024

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

Announcement

#MedSafetyWeek

Health Canada is joining the World Health Organization's annual #MedSafetyWeek social media campaign to promote adverse reaction (AR) reporting from November 4 to 10, 2024.

Adverse reactions contribute significantly to global morbidity and mortality. At the point that health products are approved for the market, most would have only been tested for short-term safety and efficacy in a limited number of carefully selected individuals. Health product safety knowledge evolves over time. A new risk may become evident once a product is used by a broader population, for a longer duration of time and/or under different conditions than those studied. As such, healthcare professionals are encouraged to report ARs to Health Canada's Canada Vigilance Program. Increased reporting contributes to the Department's post-market surveillance activities, and provides information to help ensure that the benefits of the health product continue to outweigh the risks.

Furthermore, Health Canada collaborates with international drug safety surveillance organizations, such as the World Health Organization's Programme for International Drug Monitoring, by sharing safety information gathered through AR reports.

To learn more about the #MedSafetyWeek campaign, stay tuned to Health Canada's social media channels starting November 4, 2024:

Healthy Canadians

Health Canada

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 2024 by Health Canada.

JAMP-Clopidogrel and AG-Clopidogrel

JAMP Pharma Corporation and Angita (AG) Pharma Inc. have recalled all lots of JAMP-Clopidogrel and AG-Clopidogrel 75 mg tablets as some tablets may weigh less or more than they should, meaning patients could unexpectedly receive a lower or higher dose than intended.

Advisory: JAMP-Clopidogrel and AG-Clopidogrel
Type 1 drug recall: JAMP-Clopidogrel
Type 1 drug recall: AG-Clopidogrel

M-Eslon (morphine sulfate)

Ethypharm Inc. recalled one lot of M-Eslon (morphine sulfate) extended release (ER) capsules because some bottles labelled as M-Eslon 30 mg ER may contain 60 mg capsules. This issue could lead to patients receiving a 60 mg dose instead of their prescribed 30 mg dose, which could result in an overdose and pose serious health risks.

Advisory: M-Eslon (morphine sulfate)
Type 1 drug recall: M-Eslon (morphine sulfate)

Olanzapine

Health Canada reviewed the potential risks of syndrome of inappropriate secretion of antidiuretic hormone (SIADH) and hyponatremia with the use of olanzapine. While a definitive link could not be confirmed, Health Canada's review of the available information could not rule out a possible link. Health Canada will work with the manufacturers to update the Canadian product monograph for all olanzapine-containing products to include the potential risks of SIADH and hyponatremia.

Safety Summary Review: Olanzapine

Panhematin (hemin for injection)

One lot of Panhematin 268 mg/vial powder for solution was recalled as sterility may be compromised in the affected lot.

Type 1 drug recall: Panhematin (hemin for injection)

Refresh Lacri-Lube eye ointment

AbbVie Corporation of Canada recalled all lots of Refresh Lacri-Lube eye ointment because some tubes may leak, which could lead to contamination with bacteria and other microbes and the risk of infection.

Advisory: Refresh Lacri-Lube eye ointment

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

NEW HEALTH PRODUCT SAFETY INFORMATION

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

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.

Leqvio (inclisiran)

The *Instructions for Use and Handling (For Healthcare Professionals)* found in the Canadian product monograph for Leqvio has been updated with information to help prevent the risk of **needle clogging, which can lead to an inability to depress the plunger and inject the dose.**

Key messages for healthcare professionals:[1]

- **Do not** remove the needle cap until you are ready to inject.
- Early removal of the needle cap prior to injection can lead to drying of the drug product within the needle, which can result in needle clogging.
- If you cannot depress the plunger following insertion of the needle, use a new pre-filled syringe.

Reference

1. *Leqvio (inclisiran injection)* [product monograph]. Montreal (QC): Novartis Pharmaceuticals Canada Inc.; 2024.

Provera and Depo-Provera (medroxyprogesterone acetate)

The *Warnings and Precautions* and *Patient Medication Information* sections of the Canadian product monographs for Provera and Depo-Provera have been updated with the risk of **meningioma**.

Key messages for healthcare professionals:[1,2]

- Meningiomas have been reported following long-term administration of progestins, including medroxyprogesterone acetate (MPA).
- MPA should be discontinued if a meningioma is diagnosed.
- Caution is advised when recommending medroxyprogesterone to patients with a history of meningioma.

Reference

1. *Provera (medroxyprogesterone acetate tablets)* [product monograph]. Kirkland (QC): Pfizer Canada ULC, 2024.
2. *Depo-Provera (medroxyprogesterone acetate injectable suspension)* [product monograph]. Kirkland (QC): Pfizer Canada ULC, 2024.

Zeposia (ozanimod)

The *Warnings and Precautions* and *Adverse Reactions* (*Post-Market Adverse Reactions*) sections of the Canadian product monograph for Zeposia have been updated with the risk of **liver injury and acute liver failure**.

Key messages for healthcare professionals:[1]

- Clinically significant liver injury and acute liver failure requiring liver transplant have occurred in patients treated with Zeposia in the post-marketing setting.
- Signs of liver injury, including elevated serum hepatic enzymes and elevated total bilirubin, with or without clinical symptoms, have occurred as early as 10 days after the first dose.
- During treatment with Zeposia, and in the absence of clinical symptoms, monitor liver function by evaluating liver transaminase and total bilirubin levels at months 1, 3, 6, 9 and 12 after initiating treatment, and at regular intervals thereafter.

Reference

1. *Zeposia (ozanimod)* [product monograph]. Saint-Laurent (QC): Bristol-Myers Squibb Canada; 2024.

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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