Health Canada Santé Canada

Canada

Health Product InfoWatch

May 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

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 April 2024 by Health Canada.

Cisatracurium Omega (Cisatracurium Besylate Injection 2 mg/mL)

Due to a shortage of Cisatracurium Omega (Cisatracurium Besylate Injection 2 mg/mL) in Canada and given the medical necessity of this product, Health Canada has permitted the exceptional, temporary importation and sale of Italian-authorized Cisatracurio Hikma 2 mg/mL with Italian-only labels. Healthcare professionals should be aware that there are important differences between the Italian-authorized Cisatracurio Hikma 2 mg/mL and the Canadian-authorized Cisatracurium Omega products. Refer to the Canadian product monograph for Cisatracurium Omega Single Dose, by Omega Laboratories Limited, for information on proper use.

Health Product Risk Communication: Cisatracurium Omega (Cisatracurium Besylate Injection 2 mg/mL)

JAMP Guanfacine XR

JAMP Pharma Corporation recalled one lot of JAMP Guanfacine extended release (XR) 4 mg tablets as some tablets may have been contaminated with foreign matter during manufacturing. The foreign matter, which is composed of a combination of cellulose, lubricant oil, calcium, and/or iron oxide, causes brown or amber-coloured staining on the tablet. These substances are not expected to pose any serious health risks; however, it is recommended that the medication be replaced if stains are identified.

Advisory: JAMP Guanfacine XR

Neulasta (pegfilgrastim)

This safety review evaluated the risks of Stevens-Johnson syndrome and toxic epidermal necrolysis associated with the use of Neulasta. Health Canada's review did not find sufficient evidence to support a link. Health Canada will continue to monitor the safety of Neulasta.

Summary Safety Review: Neulasta (pegfilgrastim)

PMS-Duloxetine

Affected lots of PMS-Duloxetine 30 mg and 60 mg capsules have been recalled as they exceeded the interim acceptable intake limit for *N*-nitroso-duloxetine (NDLX).

Type 1 drug recall: PMS-Duloxetine 30 mg
Type 1 drug recall: PMS-Duloxetine 60 mg

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 Jug City store in Scarborough, ON
Advisory: Unauthorized health products seized from Vanette Keast Health Consulting in Red Deer, Alberta
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.

Losec (omeprazole) and Losec Mups (omeprazole magnesium)

The *Warnings and Precautions, Adverse Reactions (Post-Market Adverse Reactions)*, and *Patient Medication Information* sections of the Canadian product monographs for Losec and Losec Mups have been updated with the risk of **acute tubulointerstitial nephritis.**

Key messages for healthcare professionals:[1,2]

- Acute tubulointerstitial nephritis (TIN) has been observed in patients taking omeprazole and may occur at any point during omeprazole therapy.
- Acute TIN can progress to renal failure.
- Omeprazole should be discontinued in case of suspected TIN, and appropriate treatment should be promptly initiated.
- Patients should be advised to consult their healthcare professional if they experience symptoms suggestive of inflammation of the kidney (decreased volume of urine, blood in the urine, fever, rash, joint stiffness).

Health Canada, in collaboration with manufacturers, will be working to include similar information about the risk of acute TIN in the Canadian product monographs for all authorized proton pump inhibitors in Canada.

References

1. *Losec (omeprazole delayed release capsules)* [product monograph]. Greifswald (Germany): Cheplapharm Arzneimittel GmbH, 2023.
2. *Losec Mups (omeprazole magnesium delayed release tablets)* [product monograph]. Greifswald (Germany): Cheplapharm Arzneimittel GmbH, 2023.

Vyvanse (lisdexamfetamine dimesylate)

The *Warnings and Precautions* and *Adverse Reactions (Post-Market Adverse Reactions)* sections of the Canadian product monograph for Vyvanse have been updated with the risk of **QTc prolongation**.

Key messages for healthcare professionals:[1]

- Lisdexamfetamine dimesylate has been shown to prolong the QTc interval in some patients.
- Vyvanse should be used with caution in patients with a prolonged QTc interval, those treated with drugs affecting the QTc interval, or those with relevant pre-existing cardiac disease or electrolyte disturbances.
- As a reminder, Vyvanse is contraindicated in patients with symptomatic cardiovascular disease and also in patients with moderate to severe hypertension.

Reference

1. *Vyvanse (lisdexamfetamine dimesylate)* [product monograph]. Toronto (ON): Takeda Canada Inc., 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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