



Health Product InfoWatch

July 2024

REPORTING ADVERSE REACTIONS

Canada Vigilance Program
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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	2
Accel-Ondansetron ODT, Mint-Betahistine and PMS-Pirfenidone	
Albrioza (sodium phenylbutyrate and ursodoxicoltaurine)	
Carbamazepine extended-release tablets	
Dianeal PD4 2.5% dextrose and physioneal 40 2.27% glucose peritoneal dialysis solutions	
Isotretinoin	
JAMP Digoxin	
Ratio-Ectosone (TEVA-Ectosone) 0.05% mild lotion	
Unauthorized Health Products	
NEW HEALTH PRODUCT SAFETY INFORMATION	4
<i>Product monograph update</i>	
Chaste tree (<i>Vitex agnus-castus</i>)	
Helpful links	4
Contact us	4
Copyright	5

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 June 2024 by Health Canada.

Accel-Ondansetron ODT, Mint-Betahistine and PMS-Pirfenidone

All lots of Accel-Ondansetron ODT (4 mg and 8 mg), Mint-Betahistine (8 mg, 16 mg and 24 mg) and PMS-Pirfenidone (267 mg and 801 mg) tablets were recalled due to concerns about the integrity of tests that are used to show that their generic prescription drugs work the same as brand-name versions. At Health Canada's request, the companies have stopped sale until they can provide additional information to demonstrate that the products are safe and effective.

[Advisory: Accel-Ondansetron ODT, Mint-Betahistine and PMS-Pirfenidone](#)

[Type 1 drug recall: Accel-Ondansetron ODT](#)

[Type 1 drug recall: Mint-Betahistine](#)

[Type 1 drug recall: PMS-Pirfenidone](#)

Albrioza (sodium phenylbutyrate and ursodoxicoltaurine)

In 2022, Albrioza was authorized under the Notice of Compliance with conditions policy for the treatment of patients with amyotrophic lateral sclerosis (ALS), based on results from a Phase 2 clinical study. Authorization was contingent on verification of clinical benefit in a Phase 3 study. The Phase 3 confirmatory study did not meet its primary or secondary endpoints. Amylyx Pharmaceuticals, Inc. will withdraw Albrioza from the Canadian market by December 31, 2024. New patients should not be initiated on Albrioza. For patients currently receiving treatment, Albrioza is now available only under Amylyx Pharmaceuticals, Inc.'s Patient Support Program.

[Health Product Risk Communication: Albrioza \(sodium phenylbutyrate and ursodoxicoltaurine\)](#)

Carbamazepine extended-release tablets

Due to a shortage of carbamazepine extended-release tablets in Canada and given the medical necessity of this anticonvulsant drug, Health Canada has permitted the exceptional, temporary importation and sale of USA-authorized Carbamazepine Extended-Release Tablets, USP with English-only labels. There are differences in formulation and physical appearance between the USA-authorized and Canadian-authorized products.

[Health Product Risk Communication: Carbamazepine extended-release tablets](#)

Dianeal PD4 2.5% dextrose and Physioneal 40 2.27% glucose peritoneal dialysis solutions

Certain lots of Dianeal and Physioneal peritoneal dialysis solutions were recalled because of possible leakage at the connection site. The affected lots were distributed in Canada between March 6, 2024 and May 29, 2024.

[Advisory: Dianeal PD4 2.5% dextrose and Physioneal 40 2.27% glucose peritoneal dialysis solutions](#)

[Type 1 drug recall: Dianeal PD4 2.5% dextrose and Physioneal 40 2.27% glucose peritoneal dialysis solutions](#)

Isotretinoin

This safety review evaluated the risk of sexual dysfunction, including persistent sexual dysfunction after drug discontinuation, with the use of isotretinoin-containing products. Health Canada's review of the available information concluded that a link could not be ruled out. Health Canada is working with the manufacturers to update and align the Canadian product monograph for all isotretinoin-containing products. Health Canada will work with the manufacturers to implement additional measures to inform patients of this potential risk.

[Safety Summary Review: Isotretinoin](#)

JAMP Digoxin

JAMP Pharma Corporation recalled one lot of JAMP Digoxin 0.0625 mg tablets as the affected lot may contain over-sized tablets.

[Type 1 drug recall: JAMP Digoxin](#)

Ratio-Ectosone (TEVA-Ectosone) 0.05% mild lotion

Teva Canada Ltd. recalled one lot of ratio-Ectosone (TEVA-Ectosone) 0.05% mild lotion in 60 mL bottles. This action follows testing that detected an impurity, betamethasone enol aldehyde, above the accepted limit in the affected lot.

[Advisory: Ratio-Ectosone \(TEVA-Ectosone\) 0.05% mild lotion](#)

[Type 1 drug recall: Ratio-Ectosone \(TEVA-Ectosone\) 0.05% mild lotion](#)

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: Absorbable \(dissolvable\) threads used in cosmetic thread lift procedures](#)

[Advisory: Poppers](#)

[Advisory: Unauthorized injectable drug products sold illegally on Quadragen and Advanced Research websites](#)

[Advisory: Unauthorized Korean-labelled Festal Plus tablets, seized from GD Health Town in Coquitlam, B.C.](#)

[Advisory: Unauthorized sexual enhancement products](#)

[Advisory: Unauthorized workout supplements](#)

NEW HEALTH PRODUCT SAFETY INFORMATION

The following topic has been selected to raise awareness and encourage reporting of adverse reactions.

Product monograph update

The following safety labelling update, which was recently made to the single ingredient monograph, has been included for your awareness. Canadian single ingredient or product monographs for Natural Health Products can be accessed through Health Canada's [Natural health products ingredients database](#).

Chaste tree (*Vitex agnus-castus*)

The *Contraindications* section of the Health Canada monograph for the natural health product ingredient Chaste tree (*Vitex agnus-castus*) for oral administration has been updated.

Key message for healthcare professionals:¹

- Chaste tree should not be used during pregnancy, breastfeeding, or while attempting to conceive without prior consultation with a healthcare practitioner, provider, or professional.

Reference

1. *Chaste tree (Vitex agnus-castus)*[natural health product monograph]. Ottawa (ON): Health 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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