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Health Product InfoWatch

February 2024

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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](#).

HEALTH PRODUCTS MENTIONED IN THIS ISSUE

Pharmaceuticals and biologics

Allergenic Extract Non Pollens
Allergenic Extract Pollens
Colistin (colistimethate sodium)

Natural and non-prescription health products

Pediatrix Acetaminophen Oral Solution for children

Other

Unauthorized health products

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 January 2024 by Health Canada.

Colistin (colistimethate sodium) Summary Safety Review	This safety review evaluated the risk of pseudo-Bartter syndrome associated with colistin (colistimethate sodium)-containing products. Health Canada's review of the available information found a link. Health Canada is working with the manufacturers to update the Canadian product monograph for colistin (colistimethate sodium)-containing products with a warning about reported cases of pseudo-Bartter syndrome.
Pediatric Acetaminophen Oral Solution for children Advisory	Teva Canada Ltd. recalled one lot of Pediatric Acetaminophen Oral Solution after routine product testing found a higher than acceptable amount of acetaminophen in the affected lot (approximately 185mg/5mL rather than the approved and labelled 160mg/5mL).
Unauthorized health products Unauthorized sexual enhancement 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.

NEW HEALTH PRODUCT SAFETY INFORMATION

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

Product monograph update

The following safety labelling update, which was recently made to the Canadian product monograph, has 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](#).

Allergenic Extract Pollens and Allergenic Extract Non Pollens (allergenic extracts for diagnostic use only)

The *Warnings and Precautions* and *Patient Medication Information* sections of the Canadian product monograph for Allergenic Extract Pollens and Allergenic Extract Non Pollens marketed by ALK-Abelló Pharmaceuticals, Inc. have been updated with the risk of **anaphylaxis** following false negative food allergen skin test results.

Key messages for healthcare professionals:¹

- There have been post-market reports of false negative skin test results, associated with anaphylaxis from subsequent exposure to the allergen.
- Based on the patient's clinical history, and if there is a high index of suspicion, healthcare providers should confirm negative skin testing with serologic testing by measuring specific serum IgE or with a medically-supervised oral food challenge.

There is currently a stop sale in place for the non-standardized peanut extract and for the non-standardized pecan extract products marketed by ALK-Abelló Pharmaceuticals, Inc.

Reference

1. *Allergenic Extract Pollens and Allergenic Extract Non Pollens (allergenic extracts for diagnostic use only)* [product monograph]. Mississauga (ON): ALK-Abelló Pharmaceuticals, 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](#)

Suggestions?

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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