



Health Product InfoWatch

April 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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HEALTH PRODUCTS MENTIONED IN THIS ISSUE

Pharmaceuticals and biologics

Combination sulfamethoxazole and trimethoprim injectable and oral formulations
Ezetrol (ezetimibe)

Natural and non-prescription health products

Nicotine pouches

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 March 2024 by Health Canada.

<p>Ezetrol (ezetimibe)</p> <p>Health Product Risk Communication</p>	<p>Ezetrol (ezetimibe) may cause serious adverse reactions, including drug-induced liver injury and severe cutaneous adverse reactions such as Stevens-Johnson syndrome, toxic epidermal necrolysis, and drug reaction with eosinophilic and systemic symptoms. The Canadian product monograph (CPM) for Ezetrol has been updated to include warnings about these serious adverse reactions. Health Canada will work with the manufacturers of generic versions of ezetimibe to update their respective CPMs.</p>
<p>Nicotine pouches</p> <p>Advisory</p>	<p>Nicotine pouches are authorized only as a nicotine replacement therapy to help adults quit smoking. They should not be used recreationally, by nonsmokers, by people under the age of 18, or by others at risk of nicotine's toxic effects. Consumers should not buy or use any unauthorized nicotine pouches. Nicotine products should be kept out of the reach of children and teens at all times.</p>
<p>Unauthorized health products</p> <p>Unauthorized health products seized from online retailer “UU Zone”</p> <p>Unauthorized health products seized from Tokyo Beauty and Healthcare store in Richmond, B.C.</p> <p>Unauthorized sexual enhancement products</p> <p>Unauthorized skin lightening and skin treatment products</p>	<p>Health Canada advised Canadians about various unauthorized health products being sold at retail locations across Canada or online that may pose serious health risks.</p>

NEW HEALTH PRODUCT SAFETY INFORMATION

The following topic has been included 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](#).

Combination Sulfamethoxazole and Trimethoprim Injectable and Oral Formulations

The *Warnings and Precautions*, *Adverse Reactions*, and *Patient Medication Information* sections of the Canadian product monographs for combination sulfamethoxazole and trimethoprim injectable and oral formulations have been, or will be, updated with **the risk of haemophagocytic lymphohistiocytosis (HLH)**.

Key messages for healthcare professionals:^{1,2}

- Cases of haemophagocytic lymphohistiocytosis (HLH) have been reported very rarely in patients treated with sulfamethoxazole-trimethoprim.
- HLH is a life-threatening syndrome of pathologic immune activation characterized by clinical signs and symptoms of extreme systemic inflammation (e.g., fever, hepatosplenomegaly, hypertriglyceridaemia, hypofibrinogenaemia, high serum ferritin, cytopenias and haemophagocytosis) and is associated with high mortality rates if not recognized early and treated.
- Immediately evaluate patients who develop early manifestations of pathologic immune activation.
- If HLH is diagnosed, discontinue sulfamethoxazole-trimethoprim treatment.

References

1. *Septtra Injection (sulfamethoxazole and trimethoprim BP)* [product monograph]. Oakville (ON): Aspen Pharmacare Canada Inc.; 2024.
2. *Sulfatrim, Sulfatrim DS, Sulfatrim Pediatric (sulfamethoxazole and trimethoprim tablets USP)* [product monograph]. Vaughan (ON): AA Pharma Inc.; 2023.

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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