Health Canada Santé Canada

Canada

Health Product
InfoWatch

May 2023

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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

SUBSCRIBE

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

Precedex (dexmedetomidine hydrochloride for injection)

Thiotepa for Injection, BP

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 recalls and summaries of completed safety reviews published in April 2023 by Health Canada.

Unauthorized health products Unauthorized Kobayashi Eyebon Eye Wash and Sante FX Neo Unauthorized prescription and controlled drugs Unauthorized sexual enhancement products Unauthorized skin lightening 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 selected 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 selected 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.

Precedex (dexmedetomidine hydrochloride for injection)

The *Warnings and Precautions* and *Patient Medication Information* sections of the Canadian product monograph for Precedex have been updated with the risk of **increased mortality in patients aged 65 years and younger**.

Key messages for healthcare professionals:[1]

- In a published pragmatic controlled trial (SPICE III), 3904 ventilated critically ill adult intensive care unit patients were randomized to either dexmedetomidine as the primary sedative or usual care. There was no overall difference in 90-day mortality between the dexmedetomidine group and the usual care group (mortality of 29.1% in both groups), but heterogeneity of effect from age on mortality was observed.
- In a published subsequent analysis of the SPICE III study, dexmedetomidine was associated with increased mortality in patients aged 65 years and younger (odds ratio 1.26; 95% confidence interval 1.02 to 1.56) compared to usual care.
- Although the mechanism is not known, the heterogeneity of effect from age on mortality was most prominent in patients admitted for reasons other than post-operative care and increased

with the increasing severity of disease as per Acute Physiology and Chronic Health Evaluation (APACHE) II scores (without the age component).
- The significance of these findings is unknown, but they should be weighed against the clinical benefit expected from dexmedetomidine compared to alternative sedatives in younger patients.

Reference

1. *Precedex (dexmedetomidine hydrochloride for injection)* [product monograph]. Kirkland (QC): Pfizer Canada ULC, 2023.

Notice of market authorization with conditions

*A Notice of Compliance with Conditions (NOC/c) is a form of market authorization with conditions granted to a product on the basis of **promising** evidence of clinical effectiveness following review of the submission by Health Canada. Communicating a NOC/c is intended to raise awareness on the details of the drug and the type of authorization granted.*

Healthcare professionals are encouraged to report to Health Canada any adverse reactions suspected of being associated with marketed health products, including drugs authorized under the NOC/c policy.

The content of these notices reflects current information at the time of publication. Conditions associated with the NOC/c will remain until they have been fulfilled and authorized by Health Canada. For the most up-to-date information, consult Health Canada's NOC database.

THIOTEPA FOR INJECTION, BP: Authorization with conditions

Health Canada has issued a Notice of Compliance, under the NOC/c policy, for THIOTEPA FOR INJECTION, BP, lyophilised powder for infusion upon reconstitution and dilution, 15 mg or 100 mg, intravenous. THIOTEPA FOR INJECTION, BP is indicated in combination with other chemotherapeutic products as part of a high-dose chemotherapy consolidation regimen followed by autologous stem cell transplantation for adult patients with central nervous system lymphoma. Patients should be advised of the conditional market authorization for this indication.

For the complete prescribing information and information available for patients/caregivers, please consult the THIOTEPA FOR INJECTION, BP Canadian product monograph. The product monograph can be accessed through Health Canada's Drug Product Database or by contacting Hikma Canada Limited at 1-800-656-0793. Contact the company for a copy of any references, attachments or enclosures.

Helpful links

- MedEffect™ Canada
- 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: List of shortages and discontinuations
- Stop Illegal Marketing of Drugs and Devices
- List of drugs for exceptional importation and sale
- Coronavirus disease (COVID-19)
- COVID-19 list of authorized drugs, vaccines and expanded indications
- COVID-19 vaccines and treatments portal
- Reported side effects following COVID-19 vaccination in Canada

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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