



Health Product InfoWatch

November 2017

HEALTH PRODUCTS MENTIONED IN THIS ISSUE

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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](#).

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 as well as summaries of completed safety reviews* published in October 2017 by Health Canada.

Foreign health products Foreign Product Alert (3 products) Foreign Product Alert (10 products)	These foreign health products have been found by regulators in other countries to contain undeclared drug ingredients. The products are not authorized for sale in Canada and have not been found in the Canadian marketplace, but it is possible they may have been brought into the country by travellers or purchased over the Internet.
Health products containing mannitol Information Update	Health Canada is aware of recent concerns around the use of mannitol as a non-medicinal ingredient in medications for use by pregnant women. Based on Health Canada's evaluation of the evidence available to date, consumption of small quantities of sugar substitutes, including mannitol, during pregnancy does not pose a health risk.
Paradigm insulin infusion pump Summary Safety Review	This safety review evaluated the risk of device malfunctions associated with Paradigm insulin infusion pumps manufactured by Medtronic MiniMed. Health Canada performed a review to assess the effectiveness of changes to the pump following recommendations from a previous review. The current review identified additional issues relating to loose drive support caps, keypad problems and blank screens. These malfunctions may lead to the patient's blood sugar becoming too high or too low. Health Canada will monitor and reassess these issues in 2 years, including the actions taken by the manufacturer to address current issues.
Unauthorized health products Advisory: Update - 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 selected to raise awareness and, in some cases, to stimulate reporting of similar adverse reactions.

PRODUCT MONOGRAPH UPDATES

The following safety labelling updates, which were recently made to the Canadian product monograph, have been selected for your awareness. A complete list of safety labelling updates for brand name pharmaceutical drugs is available on [Health Canada's Web site](#).

Clobex shampoo (clobetasol propionate solution 0.05% w/w)

Clobex shampoo is now **contraindicated** in children under 2 years of age. This information has been included in the *Indications and Clinical Use*, *Contraindications* and *Warnings and Precautions* sections of the Canadian product monograph for Clobex shampoo.

Key messages for healthcare professionals:¹

- Clobex shampoo must not be used in children under 2 years of age.
- Use in patients between 2 and 18 years of age is not recommended.
- Hypothalamic pituitary adrenal axis suppression, Cushing's syndrome, linear growth retardation, delayed weight gain, and intracranial hypertension have been reported in children receiving topical corticosteroids.

Reference

1. *Clobex shampoo (clobetasol propionate solution 0.05% w/w)* [product monograph]. Thornhill (ON): Galderma Canada Inc.; 2017.

HELPFUL LINKS

- [MedEffect™ Canada](#)
- [Recalls and Safety Alerts Database](#)
- [Summary Safety Reviews](#)
- [New Safety 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 Register](#)
- [Drug Shortages 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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