Health Canada Santé Canada

Your health and safety… our priority. *Votre santé et votre sécurité… notre priorité.*

Health Product InfoWatch

February 2018

CONTENTS

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

- Alcaine (proparacaine hydrochloride)
- Alogliptin
- Avonex (interferon beta-1a)
- Concerta (methylphenidate hydrochloride)
- Dianeal, PD4 1.5% 5L SYSII
- Dipeptidylpeptidase-4 inhibitors
- EpiPen (epinephrine)
- HYDROmorphone hydrochloride injection USP
- Linagliptin
- Ofev (nintedanib)
- Saxagliptin
- Sitagliptin
- Zoloft (sertraline hydrochloride)

Medical Devices

- Barbed (knotless) sutures

Natural Health Products

- Flintstones Plus Iron multivitamins for children

Other

- Foreign health products
- 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.

Canada

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 January 2018 by Health Canada.

Avonex (interferon beta-1a) Summary Safety Review	This safety review evaluated the risk of sarcoidosis associated with Avonex (interferon beta-1a). Health Canada's review of the available information did not find a link. Health Canada has asked the manufacturer of Avonex to actively monitor the risk of sarcoidosis in patients worldwide and to report these to Health Canada.
Barbed (knotless) sutures Summary Safety Review	This safety review evaluated the risk of small bowel obstruction associated with barbed (knotless) sutures. Health Canada's review of the available information has confirmed the potential for barbed sutures used in surgeries in the stomach area and below to hook onto the small intestine and result in a blockage. Health Canada will work with manufacturers to update the instructions for use for all barbed sutures to include details about this potential risk.
Dianeal, PD4 1.5% 5L SYSII Advisory Drug Recall	Baxter Corporation recalled one lot (lot number W7K16T1B) of Dianeal PD4 1.5% peritoneal dialysis solution in the 5-litre bag format due to the potential presence of particulate matter within the connectors.
Dipeptidylpeptidase-4 inhibitors Summary Safety Review	This safety review evaluated the risk of bullous pemphigoid associated with dipeptidylpeptidase-4 inhibitors (gliptins): alogliptin, linagliptin, saxagliptin and sitagliptin. Health Canada's safety review concluded that there may be a link. Health Canada has asked that manufacturers update the Canadian product monographs for all DPP-4 inhibitors to contain warnings for this risk.
EpiPen (epinephrine) Information Update	Pfizer Canada advised Health Canada that there is currently a shortage of EpiPen auto-injectors in the 0.3 mg format. The shortage is reported to be due to a manufacturing disruption and is anticipated to be resolved by March 2, 2018. The shortage does not impact EpiPen Jr (0.15 mg) products, which remain available.
Flintstones Plus Iron multivitamins for children Advisory	One bottle of children's Flintstones Plus Iron multivitamins was returned to a pharmacy containing unidentified capsules instead of the proper chewable tablets. The opened bottle with the safety seal removed was returned to a Pharmaprix in Longueuil, QC, in December 2017.

Foreign health products Foreign Product Alert	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.
HYDROmorphone hydrochloride injection USP Drug Recall	HYDROmorphone hydrochloride injection USP lot number 67240DD was recalled by Pfizer Canada Inc. Product sterility may be compromised in the affected lot due to the possibility of cracked vials.
Ofev (nintedanib) Health Professional Risk Communication	Cases of drug-induced liver injury (DILI), including one fatal outcome, have been reported in patients treated with Ofev (nintedanib). Healthcare professionals are advised to monitor patients' liver transaminases and bilirubin levels just before starting treatment, at regular intervals during the first three months of treatment, and periodically thereafter or as clinically indicated. Health Canada is working with the manufacturer to include this safety information in the Canadian Product Monograph.
Unauthorized health products Advisory - Kratom and sexual enhancement products 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.

Alcaine (proparacaine hydrochloride)

The risk of **abuse or misuse** has been included in the *Warnings, Adverse Reactions,* and *Consumer Information* sections of the Canadian prescribing information for Alcaine.

Key messages for healthcare professionals:[1]

- Repeated use or abuse of this product may lead to corneal epithelial toxicity and defects, which may progress to permanent corneal damage, such as corneal opacification with accompanying loss of vision.
- Alcaine should only be put into patients' eyes by a healthcare professional and should not be dispensed for patients' own use.

Reference

1. *Alcaine (proparacaine hydrochloride)* [prescribing information]. Dorval (QC): Novartis Pharmaceuticals Canada Inc.; 2018.

Concerta (methylphenidate hydrochloride)

The risk of **cerebrovascular disorders** has been included in the *Warnings and Precautions, Adverse Reactions (Post-Market Adverse Drug Reactions)* and *Consumer Information* sections of the Canadian product monograph for Concerta.

Key messages for healthcare professionals:[1]

- Cerebrovascular disorders (including cerebral vasculitis and cerebral hemorrhage) have been reported with the use of Concerta.
- Consider cerebrovascular disorders as a possible diagnosis in any patient who develops new neurological symptoms that are consistent with cerebral ischemia during Concerta therapy. These symptoms could include severe headache, unilateral weakness or paralysis, and impairment of coordination, vision, speech, language, or memory.
- If a cerebrovascular disorder is suspected during treatment, discontinue Concerta immediately.
- In patients with pre-existing cerebrovascular disorders (e.g., aneurysm, vascular malformations/ anomalies), treatment with Concerta is not recommended.

Reference

1. *Concerta (methylphenidate hydrochloride)* [product monograph]. Toronto (ON): Janssen Inc.; 2017.

Zoloft (sertraline hydrochloride)

New information regarding the risk of **prolongation of the QTc interval** has been added to the *Precautions* and *Adverse Reactions* sections of the Canadian product monograph for Zoloft (sertraline hydrochloride).

Key messages for healthcare professionals:[1]

- Sertraline has been demonstrated to cause a concentration-dependent prolongation of the QTc interval.
- Caution should be exercised when sertraline is prescribed in patients with an increased risk of QT prolongation including but not limited to those who are suspected to be at an increased risk of experiencing torsade de pointes during treatment with a QTc-prolonging drug.

Reference

1. *Zoloft (sertraline hydrochloride)* [product monograph]. Kirkland (QC): Pfizer Canada Inc.; 2018.

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

Health Canada
Marketed Health Products Directorate
Address Locator 1906C
Ottawa ON K1A 0K9
Telephone: 613-954-6522
Fax: 613-952-7738

Copyright

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.

Pub.: 170363
ISSN: 2368-8025