Health Canada Santé Canada

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

# Health Product InfoWatch

September 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**

- Azithromycin
- Epinephrine auto-injectors
- Flarex (fluorometholone acetate ophthalmic suspension)
- Methadose, Metadol-D (methadone hydrochloride)
- Opioids
- Orgalutran (ganirelix acetate injection)
- Prednisone and prednisolone
- Valsartan-containing drugs

**Medical Devices**

- Class II, III and IV medical devices

**Natural Health Products**

- Jian Pai Natural Skin Care Cream

**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.

Canada

## ANNOUNCEMENT

### Change to medical device audit process impacting product availability

Health Canada is requiring all Class II, III and IV medical device manufacturers to comply with a new audit program called the Medical Device Single Audit Program (MDSAP) by January 1, 2019.

It is anticipated that some manufacturers, instead of conforming to the new MDSAP requirements, may be cancelling their medical device licences and discontinuing the sale of their products as early as November 1, 2018. Healthcare professionals should discuss with their suppliers if they have any concerns regarding the ongoing availability of their current products.

A list of medical devices that are currently licensed for sale in Canada is available on the Medical Devices Active Licence Listing (MDALL).

**Did you know?**

The Medical Device Single Audit Program (MDSAP) is a program that allows the conduct of a single regulatory audit of a medical device manufacturer's quality management system that satisfies the requirements of multiple regulatory agencies. It will replace the current Canadian Medical Devices Conformity Assessment System (CMDCAS). In Canada, all manufacturers must make this transition to meet the quality management system requirements of the *Medical Devices Regulations.*

For more information on MDSAP please visit Health Canada's Web site.

## 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 August 2018 by Health Canada.*

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|---|---|
| **Azithromycin**<br><br>Information Update | Health Canada warned Canadians of the potential risk of cancer relapse in patients with cancer of the blood and lymph nodes who have undergone stem cell transplant and are taking long-term azithromycin. The drug was being tested in clinical trials outside Canada with the goal of preventing bronchiolitis obliterans syndrome. Cancer patients who have undergone stem cell transplants from donors are at risk of developing this condition. However, a clinical trial in France has found an increased risk of cancer recurrence with long-term use of azithromycin in stem cell transplant patients. |
| **Epinephrine auto-injectors**<br><br>Health Professional Risk Communication<br>Prescribing Information | As an emergency measure in response to the ongoing shortages of EpiPen (0.3 mg) and EpiPen Jr (0.15 mg), the Minister of Health signed an Interim Order to facilitate the import of AUVI-Q epinephrine auto-injectors in 0.3 mg and 0.15 mg dosage formats to Canada. AUVI-Q is marketed by Kaléo in the U.S. and has been approved by the U.S. Food and Drug Administration. Both Epipen and AUVI-Q deliver the same labelled dose of epinephrine, however, AUVI-Q unlike EpiPen, has a retractable needle as well as an electronic voice instruction system. English and French prescribing information for AUVI-Q is available on Health Canada's Web site. |

| | |
|---|---|
| **Jian Pai Natural Skin Care Cream**<br><br>Advisory | Health Canada testing of "Jian Pai Natural Skin Care Cream," (NPN 80038015) also called ''Yikangshuang," found that it contains two antifungal drugs (fluconazole and miconazole) that are not listed on the product label. |
| **Methadose, Metadol-D (methadone hydrochloride)**<br><br>Summary Safety Review | This safety review evaluated the risk of serious harm, including death, in children breastfed by mothers in methadone treatment. Health Canada's review of the available information found that there may be a link. Health Canada will be working with the manufacturers of Methadose and Metadol-D to strengthen their product information to warn of the risk of serious harm, including death, in children exposed to methadone through breast milk. |
| **Prednisone and prednisolone**<br><br>Summary Safety Review | This safety review evaluated the risk of scleroderma renal crisis (SRC) with the use of oral prednisone and prednisolone products in patients with systemic sclerosis. Health Canada's review of the available information has concluded that there may be a link between the use of oral prednisone and prednisolone products, especially at higher doses, and SRC in patients with systemic sclerosis. Health Canada will be working with the manufacturers to update the Canadian product monographs for oral prednisone and prednisolone products to inform about this risk. |
| **Unauthorized health products**<br><br>Unauthorized products seized in Alberta<br>Unauthorized skin creams and lotions in Quebec<br>Update - Multiple unauthorized health 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. |
| **Valsartan-containing drugs**<br><br>Information Update<br>Information Update - Estimates of health risks<br>Information Update - Second impurity | Several drugs containing valsartan were recalled by their manufacturers (a list of recalled products and a list of products that are not recalled are provided in the information update). Impurities, N-nitrosodimethylamine (NDMA) and N-nitrosodiethylamine (NDEA), both classified as probable human carcinogens, were found in the valsartan used in these products. The valsartan was supplied by Zhejiang Huahai Pharmaceuticals. |

# 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 is available on Health Canada's Product Monograph Brand Safety Updates. Canadian product monographs can be accessed through Health Canada's Drug Product Database.*

## Flarex (fluorometholone acetate ophthalmic suspension)

New information regarding the risk of **systemic corticosteroid toxicity** has been added to the *Warnings and Precautions, Drug Interactions* and *Consumer Information* sections of the Canadian product monograph for Flarex.

### Key messages for healthcare professionals:[1]

- Systemic corticosteroid adverse reactions may occur after intensive or long-term continuous ophthalmic corticosteroid therapy in predisposed patients, including children and patients treated with CYP3A4 inhibitors (e.g., ritonavir and cobicistat).
- The combination of Flarex and CYP3A4 inhibitors (including ritonavir and cobicistat) should be avoided unless the benefit outweighs the increased risk, in which case patients should be monitored for systemic corticosteroid adverse reactions.

**Reference**

1. *Flarex (fluorometholone acetate ophthalmic suspension)* [product monograph]. Dorval (QC): Novartis Pharmaceuticals Canada Inc.; 2018.

## Orgalutran (ganirelix acetate injection)

The use of Orgalutran is now **contraindicated in patients with a known hypersensitivity to rubber/latex**. The risk of allergic reactions in latex sensitive individuals has been included in the *Contraindications, Precautions, Availability of dosage forms* and *Information for the consumer* sections of the Canadian product monograph for Orgalutran.

### Key messages for healthcare professionals:[1]

- The needle shield of Orgalutran pre-filled syringe contains dry natural rubber/latex that has the potential to cause allergic reactions in latex sensitive individuals.

**Reference**

1. *Orgalutran (ganirelix acetate injection)* [product monograph]. Kirkland (QC): Merck Canada Inc.; 2018.

## ANNOUNCEMENT

### Opioid marketing and advertising - share your stories

Are you aware of inappropriate industry marketing or advertising activities and materials related to opioids?

Have you had experience with industry-sponsored courses or conferences related to opioids that have demonstrated advertising or marketing practices that could be inappropriately influencing healthcare professionals?

Have you received opioid-related information on research, presentations, speeches, or other industry activities that you would like to share with Health Canada?

We want to hear from you! The information that you provide could help inform our ongoing analysis of opioid marketing and advertising practices.

Share your written comments, images, or videos about your experiences by email at MHPD_DPSC-Advertising_Reg_Publicite@hc-sc.gc.ca

Personal information that you provide is protected under the provisions of the Privacy Act. For more information, see the Share your Stories Privacy Notice.

## HELPFUL LINKS

- MedEffect™ Canada
- Recalls and Safety Alerts Database
- 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 HC.infowatch-infovigilance.SC@canada.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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