Health Canada | Santé Canada

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

Health Product InfoWatch

December 2017

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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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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

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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 150

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 November 2017 by Health Canada.

Breast implants Summary Safety Review Health Professional Risk Communication Information Update	This safety review evaluated the risk of breast implant-associated anaplastic large cell lymphoma (BIA-ALCL). Health Canada's safety review determined that the rate of BIA-ALCL in Canada is low. Nearly all the cases were associated with implants that have a textured surface. Health Canada is working with manufacturers who will update the safety information on the product labelling for breast implants. In addition, Health Canada will actively monitor all reported Canadian cases of BIA-ALCL through a yearly follow-up with the manufacturers of breast implants. Health Canada has also communicated this information to healthcare professionals and the public.
Fluconazole 150 mg (non-prescription) Summary Safety Review	This safety review evaluated the risk of unwanted effects in pregnancy including miscarriage, stillbirth and birth defects associated with non-prescription fluconazole (oral, 150 mg). Health Canada's review found that a link cannot be made at this time based on the currently available information. The manufacturer of Diflucan ONE voluntarily updated the Canadian product monograph about these potential risks. Health Canada concluded that the proposed update for Diflucan ONE is appropriate and has recommended that the Canadian product monograph for all other non-prescription fluconazole products be updated in the same way.
Green tea extract-containing natural health products Summary Safety Review Health Professional Risk Communication Information Update	This safety review evaluated the risk of hepatotoxicity associated with green tea extract-containing natural health products. Health Canada's review concluded that there may be a link, that cases of hepatotoxicity continue to be reported, and that Canadian safety information could be stronger. Health Canada is strengthening the safety information in its Green Tea Extracts monograph and is working with manufacturers to strengthen the safety information on labels of these products. The safety review also recommended that green tea extract-containing products be used by adults only (18 years and over). These new safety warnings will be updated on product labels. Health Canada has also communicated this information to healthcare professionals and the public.
Mifegymiso (mifepristone and misoprostol) Health Professional Risk Communication Information Update	Mifegymiso is now indicated for use up to nine weeks (63 days) into a pregnancy. Modifications have been made to the Mifegymiso product monograph and the Risk Management Plan. Changes have also been made to the Distribution and Education Program in Canada.

TactiCath Quartz Summary Safety Review	This safety review evaluated the risk of cardiac tamponade associated with TactiCath Quartz. Health Canada's review of the available information concluded that there is a potential link. The risk is known and labelled in the Instructions for Use for TactiCath Quartz. Health Canada encourages healthcare professionals to follow the Instructions for Use given by the manufacturer when using this device to treat patients and to report any side effects associated with its use.
Unauthorized health products Advisories: E-Fong XuDuan Concentrated Herb Tea 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.

Eprex (epoetin alfa)

The risk of **severe cutaneous adverse reactions (SCARs)** including Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN), which can be life-threatening or fatal, has been included in the *Warnings and Precautions* and *Adverse Reactions (Post-Market Adverse Drug Reactions)* sections of the Canadian product monograph for Eprex (epoetin alfa).

Key messages for healthcare professionals:[1]

- Blistering and skin exfoliation reactions including erythema multiforme and SJS/TEN have been reported in a small number of patients treated with Eprex.
- Discontinue Eprex therapy immediately if a severe cutaneous reaction, such as SJS/TEN, is suspected.
- Permanently discontinue Eprex if SJS/TEN is confirmed.

Reference

1. *Eprex (epoetin alfa)* [product monograph]. Toronto (ON): Janssen Inc.; 2017.

Gilenya (fingolimod)

The risk of **thrombocytopenia** has been included in the *Adverse Reactions (Post-Market Adverse Reactions)* section of the Canadian product monograph for Gilenya (fingolimod).

Key messages for healthcare professionals:[1]

- Thrombocytopenia has been reported during postmarketing experience with Gilenya.
- Complete blood count should be checked before starting Gilenya therapy if no recent (i.e., within 6 months or after discontinuation of prior therapy) result is available.

Reference

1. *Gilenya (fingolimod)* [product monograph]. Dorval (QC): Novartis Pharmaceuticals 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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