Health Canada Santé Canada

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

Health Product InfoWatch

September 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

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.

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 August 2017 by Health Canada.

Aubagio (teriflunomide) Summary Safety Review	This safety review evaluated the risk of acute renal injury or nephrolithiasis associated with Aubagio (teriflunomide). Health Canada's review of the available information did not establish a link. Health Canada will continue to monitor this issue.
Desloratadine Summary Safety Review	This safety review evaluated the risk of QT interval prolongation associated with desloratadine. Health Canada's review of the available information did not establish a link. Health Canada will continue to monitor this issue.
Effient (prasugrel) Summary Safety Review	This safety review evaluated the risk of severe cutaneous adverse reactions associated with Effient (prasugrel). Health Canada's review concluded that there was not enough information available to establish a link. Health Canada will continue to monitor this issue.
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.
Hydroquinone Information Update	Hydroquinone at concentrations above 2% for use on the skin will be added to the Prescription Drug List. These products will be available by prescription only, under the oversight of a healthcare professional, rather than without a prescription.
Unauthorized health products Advisories: Aerobic Oxygen Kobayashi Eyebon Eyewash Poppers and sexual enhancement products Product containing synthetic cannabinoids Psychotic by Insane Labz 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.

Keppra (levetiracetam)

The risk of **pancytopenia** has been included in the *Warnings and Precautions* section of the Canadian product monograph for Keppra (levetiracetam). The risk of **rhabdomyolysis/blood creatine phosphokinase increase** has been included in the *Post-Market Adverse Drug Reactions* section.

Key messages for healthcare professionals:[1]

- Cases of decreased blood cell counts (neutropenia, agranulocytosis, leucopenia, thrombocytopenia and pancytopenia) have been described in association with levetiracetam administration.
- Complete blood cell counts are advised in patients experiencing important weakness, pyrexia, recurrent infections or coagulation disorders.
- Cases of rhabdomyolysis and/or blood creatine phosphokinase increase have been reported in diverse patient populations. However, patients of Japanese origin may be at higher risk.

Reference

1. *Keppra (levetiracetam)* [product monograph]. Oakville (ON): UCB Canada Inc.; 2017.

Rifadin (rifampin)

The risk of **tooth discoloration** has been included in the *Precautions, Adverse Reactions (Post-Market Adverse Drug Reactions)* and *Symptoms and Treatment of Overdosage* sections of the Canadian product monograph for Rifadin (rifampin).

Key messages for healthcare professionals:[1]

- Rifadin and its metabolites may produce a discoloration (yellow, orange, red, brown) of the teeth, urine, feces, saliva, sputum, sweat and tears.
- Tooth discoloration may be permanent.
- In the event of an overdosage, the intensity of the discoloration may be proportional to the amount ingested.

Reference

1. *Rifadin (rifampin)* [product monograph]. Laval (QC): sanofi-aventis 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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