Health Canada Santé Canada

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

Health Product InfoWatch

April 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

Alysena 21 and 28 (levonorgestrel and ethinyl estradiol)
Cardizem CD (diltiazem hydrochloride)
Clozapine
Fibristal (ulipristal acetate)
Halaven (eribulin mesylate)
Sodium Chloride Injection 0.9%, 250 mL
Zinbryta (daclizumab beta)

Medical Devices

Omnipod Insulin Management System
Ophthalmic Viscosurgical Devices
SurgiWrap adhesion barrier film

Natural Health Products

"Beyond Yourself Multi Athlete"
"Leopard Miracle of Honey"

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

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 March 2018 by Health Canada.

Alysena 21 and 28 (levonorgestrel and ethinyl estradiol) Advisory	Further to a recent advisory about the recall of one lot of Alysena 28 because of chipped pills, Health Canada informed Canadians that all lots of both Alysena 21 and Alysena 28 may have chipped pills. Health Canada reminded women to always check their pills carefully before taking them.
"Beyond Yourself Multi Athlete" Advisory	"Beyond Yourself Multi Athlete" multivitamin sold in bulk was seized from several Shop Santé stores in Quebec because it may pose serious health risks. While this multivitamin is labelled as approved by Health Canada (NPN 80053503), the dosing instructions and brand name on the package do not match Health Canada's authorization. Consumers following the package instructions would be exposed to excessively high doses of vitamins A and K. Health Canada has suspended licence NPN 80053503.
Clozapine Summary Safety Review	This safety review evaluated the risk of agranulocytosis associated with clozapine. Health Canada's review concluded that the monitoring measures in place for agranulocytosis are acceptable, but that the risk should still be monitored. Therefore, Health Canada has asked that the manufacturers of clozapine submit a report, in 2 years, of all the data collected related to the risk of agranulocytosis when clozapine is used.
Fibristal (ulipristal acetate) Information Update	Health Canada will be conducting a safety review of Fibristal (ulipristal acetate). The Canadian product monograph for Fibristal was updated in January 2018 to advise of rare cases of liver injury, including serious liver impairment requiring liver transplants. Since then, additional information on this issue has become available. Interim information for healthcare professionals and patients is provided in the information update.
Halaven (eribulin mesylate) Summary Safety Review	This safety review evaluated the risk of severe cutaneous adverse reactions (SCAR) associated with Halaven (eribulin mesylate). Health Canada's review concluded that there was not enough evidence to establish a direct link between the use of Halaven and the potential risk of SCAR. The current product monograph covers the potential risk of SCAR and no additional warnings are required.

"Leopard Miracle of Honey" Advisory	Two versions of the sexual enhancement product “Leopard Miracle of Honey” may pose serious health risks. Both versions are labelled as being approved by Health Canada, with NPN 80073650. Health Canada’s testing found that both versions of the product contain undeclared sildenafil. The product was not authorized to contain sildenafil. Health Canada seized the products from 2 Ontario convenience stores located in Woodbridge, ON, and suspended the product licence.
Omnipod Insulin Management System Summary Safety Review	This safety review evaluated the risk of device malfunctions associated with the Omnipod Insulin Management System. Health Canada's review concluded that there is no new safety risk for the Omnipod. The safety information for this medical device is appropriate at this time.
Ophthalmic Viscosurgical Devices Summary Safety Review	This safety review evaluated the risk of toxic anterior segment syndrome (TASS) associated with Ophthalmic Viscosurgical Devices (OVDs) manufactured by Alcon Laboratories. Health Canada’s review of the available information could not establish a link. Health Canada reminds healthcare professionals about the importance of following the Instruction for Use manuals issued by the manufacturers of OVDs and encourages reporting of adverse incidents associated with the use of OVDs.
Sodium Chloride Injection 0.9%, 250 mL Drug Recall	Baxter Corporation has recalled 0.9% Sodium Chloride Injection, 250 mL (W7I05C2) as there is a potential for leakage of the intravenous bag.
SurgiWrap adhesion barrier film Summary Safety Review	This safety review evaluated the risk of foreign body reactions (FBRs) that may mimic the local re-appearance of cancer associated with SurgiWrap adhesion barrier film. Health Canada’s review concluded that there is currently not enough evidence to establish a link. No Canadian reports of FBRs were found that describe this adverse incident. The safety information for this product is suitable at this time as the Instructions for Use manual already contains a warning that FBRs may occur. Healthcare professionals are encouraged to consider this potential risk for the management of patients with cancer when SurgiWrap is used.
Unauthorized health products "Multi-Vitamines" Injectable products and unauthorized prescription drugs Unauthorized injectable drugs and medical devices Update - Multiple unauthorized 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.

Zinbryta (daclizumab beta) Health Professional Risk Communication	Following reports of serious inflammatory brain disorders, including immune-mediated encephalitis and meningoencephalitis, the manufacturer has decided to voluntarily withdraw Zinbryta from the Canadian market. All treating healthcare professionals were advised to immediately contact patients in their care who have been prescribed Zinbryta, and to initiate alternative treatment options as soon as medically appropriate. Given Zinbryta's potential for liver injury, patients discontinuing the product should have serum transaminase levels and total bilirubin levels monitored monthly, for 6 months after receiving their last dose of Zinbryta. Healthcare professionals should inform their patients that adverse reactions may also occur up to 6 months after discontinuation and to contact their physician immediately if any new symptoms occur.

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.

Cardizem CD (diltiazem hydrochloride)

The risk of **bronchospasm, including asthma aggravation**, has been included in the *Precautions* and *Adverse Reactions* sections of the Canadian product monograph for Cardizem CD.

Key messages for healthcare professionals:[1]

- Bronchospasm, including asthma aggravation, has been reported with the use of diltiazem, especially in patients with pre-existing bronchial hyper-activity and after dose increase.
- Patients should be monitored for signs and symptoms of respiratory impairment during diltiazem therapy.

Reference

1. *Cardizem CD (diltiazem hydrochloride)* [product monograph]. Laval (QC): Valeant Canada LP; 2018.

VACCINE SAFETY BIANNUAL SUMMARY

Health Canada and the Public Health Agency of Canada (PHAC) share the responsibility of monitoring the safety of vaccines in Canada.

Market authorization holders are required to report serious adverse events following immunization (AEFIs) to the Canada Vigilance Program in Health Canada. The Canada Vigilance Program also receives voluntary AEFI reports from healthcare professionals and consumers.

Provincial and territorial public health authorities report AEFIs from publicly funded vaccine programs to the Canadian Adverse Events Following Immunization Surveillance System (CAEFISS) in PHAC to monitor the safety of immunization programs.

Report for January 1, 2017 to June 30, 2017

This biannual vaccine safety summary includes AEFI reports received by the Canada Vigilance Program between January 1, 2017 and June 30, 2017. To access reports published by CAEFISS, please visit the CAEFISS Web site.

- From January 1, 2017 to June 30, 2017, the Canada Vigilance Program received 222 reports* of adverse events following immunization for which vaccines were the suspected cause.

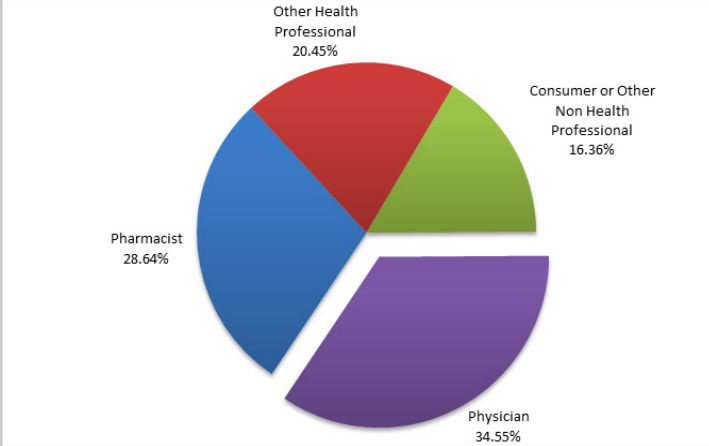

Figure 1: Total number of AEFI reports received, by type of originating reporter

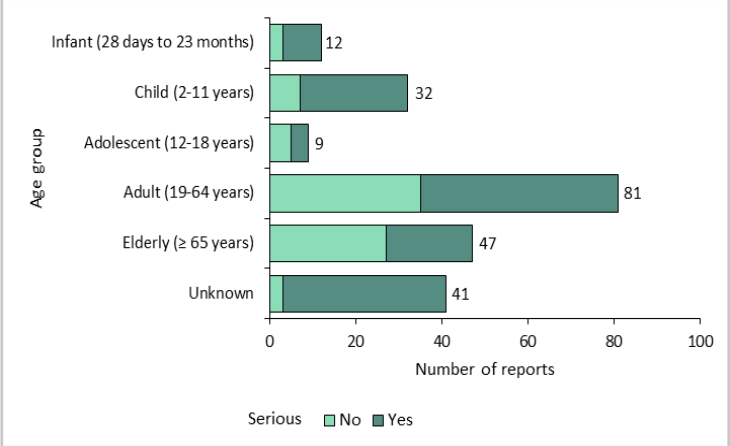

Figure 2: Total number of AEFI reports received, by age group

- There were 142 (64%) serious reports. Most of these involved patients with underlying medical conditions and were unlikely related to the vaccination.
- The highest number of reports (serious and non-serious) involved herpes zoster vaccine (22%) and influenza vaccines (21%), followed by pneumococcal vaccines (18%).
- The most frequently reported adverse events (serious and non-serious) included drug ineffectiveness, injection site erythema, pruritus, pyrexia, and injection site swelling. These are common adverse events following vaccination and are captured in the Canadian product monographs.
- In cases that reported drug ineffectiveness, the information provided was not sufficient to adequately assess the causal association with the vaccine because one or more elements of the following information was not reported: vaccination according to the recommended schedule, pre-existing condition at the time of vaccination, concomitant treatment(s), laboratory test to confirm the serotype, and time to onset.

- No new safety signals (potential safety issues) were identified during this period.
- The benefits of vaccines authorized in Canada continue to outweigh the risks.
- Health Canada, in collaboration with the Public Health Agency of Canada, will continue to closely monitor the safety of vaccines authorized in Canada and will take appropriate action if any new health risks are identified.

For additional information, contact the Marketed Health Products Directorate.

Note that because of updated information received by the Canada Vigilance Program, there may be differences in the number of AEFI reports and adverse events retrieved at different dates.

* Glossary of Fields in the Canada Vigilance Adverse Reaction Online Database

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 HC.infowatch-infovigilance.SC@canada.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