Health Canada Santé Canada

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

Health Product InfoWatch

August 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.

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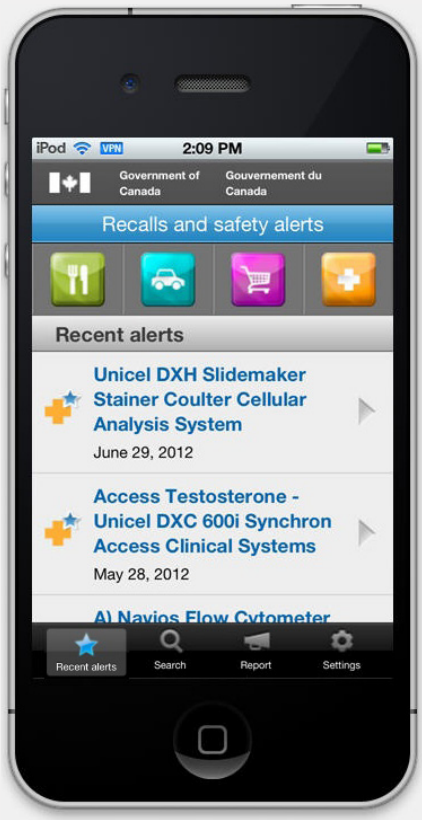
This monthly publication is intended primarily for healthcare professionals and includes information on pharmaceuticals, biologics, medical devices and natural health products. It provides a summary of key health product safety information published in the previous month by Health Canada, as well as 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

ANNOUNCEMENT



Recalls and safety alerts mobile application

The free "Recalls and safety alerts" application for Apple, Android and BlackBerry delivers up-to-date and reliable health and safety information right to your mobile phone.

An up-to-date list of health product recalls and advisories can be found by clicking the health products button. This app also offers a search option which will provide the latest information on a specific health product.

The "Recalls and safety alerts" application can be downloaded from your smartphone using:

Available at amazon apps

Available on the App Store

Download for Android

For more information please visit the recalls and safety alerts mobile application Web page.

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 July 2017 by Health Canada.

Amino-acid solutions for parenteral nutrition Summary Safety Review	This safety review evaluated the risk of death in premature infants when fed with amino-acid solutions for parenteral nutrition that were not protected from light when administered. Health Canada's review concluded that there was not enough information available to confirm a link. Health Canada will continue to monitor this issue.
Erwinase for injection Health Professional Risk Communication	The Erwinase product from batch CAMR 182 H117 that is now being distributed in Canada has Canadian labelling and not UK labelling as mentioned in previous risk communications. If particulate matter is observed elsewhere other than on the underside of the stopper (e.g., on or in the product) before or after reconstitution, the product should not be administered and should be retained for collection. A standard 5-micron filter needle should be used to withdraw the reconstituted product from the vial prior to administration as a precautionary measure.
Foreign health products Foreign Product Alert	These foreign health products have been found by regulators in other countries to contain undeclared drug ingredients. These 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.
Gentamicin Injection USP Health Professional Risk Communication	Twelve lots of Gentamicin Injection USP (10 mg/mL and 40 mg/mL) manufactured at Sandoz Canada Inc. may contain traces of histamine. Histamine administered intravenously or intramuscularly could potentially lead to signs and symptoms of anaphylaxis, particularly in pediatric patients and patients with severe renal impairment. Although the likelihood of this adverse event is rare, all patients administered Gentamicin Injection USP from the affected lots should be closely monitored for adverse reactions associated with elevated levels of histamine.
Intraocular lenses Summary Safety Review	This safety review evaluated the risk of the development of glistening associated with the use of intraocular lenses. Health Canada's review concluded that the available evidence is not strong enough to determine how or why glistening develops, and if it changes the quality of a person's vision. Health Canada will continue to monitor this issue.

NovoPen Echo and NovoPen 5 insulin cartridge holders Advisory	Insulin cartridge holders used in certain lots of NovoPen Echo and NovoPen 5 insulin pens were recalled by Novo Nordisk A/S. The company detected that the cartridge holders may crack or break if exposed to certain chemicals, such as some cleaning agents, which could result in a smaller dose of insulin than expected.
PMS-Propofol Drug Recall	PMS-Propofol (lot number A060200) was recalled by Pharmascience Inc. as the affected lot may contain glass particles.
RestoraLAX 30 + 7 Bonus Pack and RestoraLAX 45 + 10 Value Pack Advisories: RestoraLAX 30 + 7 Bonus Pack RestoraLAX 45 + 10 Value Pack Drug recalls: RestoraLAX 30 + 7 Bonus Pack RestoraLAX 45 + 10 Value Pack	Health Canada advised Canadians that Bayer Inc. recalled specific lots of RestoraLAX 30 + 7 Bonus Pack sold at various retailers across Canada and specific lots of RestoraLAX 45 + 10 Value Pack sold at Costco Canada. The recalled products may contain deposits such as clumps or lumps which may pose a choking hazard.
Unauthorized health products Advisories: Black Mamba Premium Fluffy Unicorn Kratom products Selekta Pregnenolone	Health Canada advised Canadians about various unauthorized health products being sold at retail locations across Canada or online.

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.

Invokana (canagliflozin) and Invokamet (canagliflozin and metformin)

The risk of **bone fracture and decreased bone mineral density (BMD)** has been included in the *Warnings and Precautions* and *Adverse Reactions* sections of the Canadian product monographs for Invokana (canagliflozin) and Invokamet (canagliflozin and metformin).

Key messages for healthcare professionals:[1,2]

- An increased risk of bone fractures, occurring as early as 12 weeks after the onset of treatment, was observed in patients using canagliflozin.
- In a clinical trial of 714 older adults (mean age 64 years), patients randomized to canagliflozin 100 mg and 300 mg showed placebo-corrected declines in bone mineral density at the hip and lumbar spine after 2 years of treatment.
- Prior to initiating canagliflozin, it is important to consider factors that contribute to fracture risk.

References

1. *Invokamet (canagliflozin and metformin)* [product monograph]. Toronto (ON): Janssen Inc.; 2017.
2. *Invokana (canagliflozin)* [product monograph]. Toronto (ON): Janssen Inc.; 2017.

Revlimid (lenalidomide)

The risk of **rhabdomyolysis** has been included in the *Adverse Reactions* section of the Canadian product monograph for Revlimid (lenalidomide).

Key messages for healthcare professionals:[1]

- Rare cases of rhabdomyolysis have been reported in patients treated with Revlimid.
- Patients should be observed for signs of rhabdomyolysis, such as muscle pain, weakness or swelling, and dark urine.

Reference

1. *Revlimid (lenalidomide)* [product monograph]. Mississauga (ON): Celgene Inc. Canada; 2017.

Temodal (temozolomide)

The risk of **herpes simplex encephalitis** has been included in the *Warnings and Precautions* and *Adverse Reactions* sections of the Canadian product monograph for Temodal (temozolomide).

Key messages for healthcare professionals:[1]

- Cases of herpes simplex encephalitis (HSE), including cases with fatal outcomes, were reported in patients on Temodal, mostly in association with concomitant radiotherapy.
- All patients, particularly those with previous herpes simplex infection, need to be monitored for signs and symptoms of HSE during the treatment such as fever, headache, personality change, seizures, and/or vomiting.

Reference

1. *Temodal (temozolomide)* [product monograph]. Kirkland (QC): Merck Canada Inc.; 2017.

Videx EC (didanosine)

The risk of **congenital malformation** has been included in the *Warnings and Precautions* section of the Canadian product monograph for Videx EC (didanosine).

Key messages for healthcare professionals:[1]

- The Antiretroviral Pregnancy Registry has reported elevation of congenital malformation rates in infants following exposure to Videx EC during pregnancy.
- Based on human experience, Videx EC can cause congenital malformations when administered during pregnancy.
- The frequency of congenital malformations in infants exposed during the first trimester is greater than in unexposed infants.

Reference

1. *Videx EC (didanosine)* [product monograph]. Montreal (QC): Bristol-Myers Squibb Canada; 2017.

Zelboraf (vemurafenib)

The risk of **Dupuytren's contracture and plantar fascial fibromatosis** has been included in the *Warnings and Precautions* and *Adverse Reactions* sections of the Canadian product monograph for Zelboraf (vemurafenib).

Key messages for healthcare professionals:[1]

- Dupuytren's contracture and plantar fascial fibromatosis have been reported with the use of Zelboraf.
- The majority of cases were mild to moderate, but severe and disabling cases of Dupuytren's contracture have also been reported.
- These adverse reactions should be managed with dose reduction, temporary treatment interruption, or treatment discontinuation.

Reference

1. *Zelboraf (vemurafenib)* [product monograph]. Mississauga (ON): Hoffmann-La Roche Limited; 2017.

VACCINE SAFETY QUARTERLY SUMMARY

Report for October 1, 2016 to December 31, 2016

Post-market surveillance is essential to monitor the safety and effectiveness of vaccines and other health products. The monitoring of the safety of vaccines is a shared responsibility between Health Canada and the Public Health Agency of Canada (PHAC). Market authorization holders are required to report serious adverse events following immunization (AEFIs) to the Canada Vigilance Program in the Marketed Health Products Directorate at 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.

This Vaccine Safety Quarterly Summary includes AEFI reports received by the Canada Vigilance Program between October 1, 2016 and December 31, 2016. To access reports published by CAEFISS, please visit the CAEFISS Web site.

- From October 1, 2016 to December 31, 2016, the Canada Vigilance Program received 167 reports* of adverse events following immunization (AEFIs) for which vaccines were the suspected cause.
- There were 86 (52%) serious reports. Most of these involved patients with underlying medical conditions and were unlikely related to the vaccination.
- The largest proportion of reports (serious and non-serious) involved influenza vaccines (46%) followed by herpes zoster vaccine (22%) and pneumococcal vaccines (9%).
- The most frequently reported AEFIs (serious and non-serious) included injection site erythema, pruritus, headache, aggravated condition, and hypotonic-hyporesponsive episode.
    - Five of the serious reports with the event of aggravated condition were from a patient who received multiple vaccines and 13 of the serious reports of hypotonic-hyporesponsive episode were from 4 patients who received one or more vaccines.
    - All of these reports lacked sufficient information for adequate assessment. The other AEFIs are common following vaccination and are captured in the respective Canadian product monographs.
- 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 PHAC, will continue to closely monitor the safety of vaccines authorized in Canada.

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

This summary may contain duplicate reports. Duplicate reports are reports related to the same patient and event received from more than one source (e.g. pharmacist and consumer). Therefore, the sum of all reports in the line listing may exceed the total number of individual patient cases.

For additional information, contact the Marketed Health Products Directorate.

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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