Health Canada Santé Canada

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

Health Product InfoWatch

May 2016

CONTENTS

REPORTING ADVERSE REACTIONS

Canada Vigilance Program
Telephone: 1-866-234-2345
Fax: 1-866-678-6789
Online: www.health.gc.ca/medeffect

SUBSCRIBE

To receive the Health Product InfoWatch and notifications of health product advisories by email, subscribe to MedEffect™ e-Notice at www.health.gc.ca/medeffect

HEALTH PRODUCTS MENTIONED IN THIS ISSUE

Pharmaceuticals and Biologics

Bexsero (multicomponent meningococcal B vaccine [recombinant, adsorbed])
Celebrex and generics (celecoxib)
Holkira Pak (ombitasvir/paritaprevir/ritonavir and dasabuvir)
Perjeta (pertuzumab)
Technivie (ombitasvir/paritaprevir/ritonavir)
Uloric (febuxostat)
Yervoy (ipilimumab)
Zostavax (zoster vaccine live, attenuated [Oka/Merck])

Medical Devices

Cook Catheters with Beacon Tip Technology

Other

Unauthorized health products
URX Bombshell

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 as well as summaries of completed safety reviews published in April 2016 by Health Canada.

Celebrex and generics (celecoxib) Summary Safety Review	This safety review evaluated the risk of cardiovascular adverse reactions with the use of celecoxib, in comparison to other non-steroidal anti-inflammatory drugs (diclofenac, ibuprofen, naproxen). Health Canada's review concluded that celecoxib (at doses higher than 200 mg per day) may be linked with an increased risk of serious cardiovascular adverse reactions and this risk is similar to the risks linked with the use of high doses of diclofenac (≥150 mg per day) or ibuprofen (≥2400 mg per day). Additional information is being added to the prescribing information for celecoxib.
Cook Catheters with Beacon Tip Technology Health Product Risk Communication	Cook Catheters with Beacon Tip technology have been recalled due to polymer degradation of the catheter tip, which could result in tip fracture and/or separation. Healthcare professionals should return the devices. Health Canada is aware that this may cause a shortage issue. To obtain information on other products that can be used as alternatives, healthcare professionals should contact Cook Medical directly.
Perjeta (pertuzumab) Summary Safety Review	This safety review evaluated the potential risk of Stevens-Johnson Syndrome with the use of Perjeta. Health Canada's review concluded that the evidence was too limited to support a link. Health Canada has asked the manufacturer to continue to actively monitor for this risk worldwide and to report new cases to Health Canada.
Uloric (febuxostat) Summary Safety Review	This safety review evaluated the potential risk of heart failure linked with the use of Uloric. Further to the safety review, Health Canada has asked the manufacturer of Uloric to include a statement regarding the potential increased risk of heart failure in patients with pre-existing cardiovascular disease and/or risk factors in the Canadian prescribing information.
Unauthorized health products Advisory	Health Canada seized 17 unauthorized health products from Matrioshka Russian Delicatessen in Calgary, Alberta. Two unauthorized products were labelled with prescription drug ingredients (captopril and sulfanilamide). Unauthorized health products were being sold with packaging labelled in Russian, Ukrainian or Kazakh languages only, with the exception of some ingredients which were listed in English.

URX Bombshell Advisory	Health Canada advised Canadians that an unauthorized drug, URX Bombshell, labelled to contain prescription drug substances (yohimbine and rauwolfia), was being sold on Kijiji and at DiscountSupplementsCo.com.
Yervoy (ipilimumab) Summary Safety Review	This safety review evaluated the potential risk of Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) with the use of Yervoy. Health Canada's review concluded that there may be a link. Yervoy affects the immune system of the patient in a way which may increase the chances for DRESS to develop. The Canadian prescribing information for Yervoy has been updated to include this potential risk.

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.

VACCINE SAFETY REVIEW

Report for July 1, 2015 to September 30, 2015

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 Review summarizes AEFI reports received by the CanadaVigilance Program between July 1, 2015 and September 30, 2015. To access reports published by CAEFISS, please visit the CAEFISS website.

- From July 1, 2015 to September 30, 2015, the Canada Vigilance Program received 123 reports of adverse events for which vaccines were the suspected cause.

- As in the previous quarters of 2015, the majority of the reports received involved Bexsero (multicomponent meningococcal B vaccine [recombinant, adsorbed]; 37 reports) and Zostavax (zoster vaccine live, attenuated [Oka/Merck]; 25 reports).
- There were 64 (52%) serious reports. Most of these involved patients with underlying medical conditions and were unlikely related to the vaccination.
- The most frequently reported AEFIs were diarrhea, nausea, pain in the extremities, headache, malaise, myalgia, pyrexia, vaccination site erythema and fatigue. The majority of these adverse events involved Bexsero and Zostavax. These are known events following immunization and are included 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.

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.

Holkira Pak (ombitasvir/paritaprevir/ritonavir and dasabuvir), Technivie (ombitasvir/paritaprevir/ritonavir)

*The risk of **hepatic decompensation and hepatic failure in patients with cirrhosis** has been included in the Contraindications, Warnings and Precautions, Post-Market Adverse Drug Reactions, Drug Interactions and Dosage and Administration sections of the Canadian product monographs for Holkira Pak and Technivie.*

Key message for healthcare professionals:[1,2]

- Holkira Pak and Technivie are contraindicated in patients with moderate to severe hepatic impairment (Child-Pugh B and C) due to risk of potential toxicity.
- Hepatic decompensation and hepatic failure, including liver transplantation or fatal outcomes, have been reported from postmarketing sources in patients treated with Holkira Pak or Technivie with and without ribavirin. Most patients with these severe outcomes had evidence of advanced or decompensated cirrhosis prior to initiating therapy.
- Prior to initiation of therapy, assess for laboratory and clinical evidence of hepatic decompensation (i.e., ascites, hepatic encephalopathy or variceal hemorrhage).
- For patients with cirrhosis*, hepatic laboratory testing including direct bilirubin levels should be performed at baseline, during the first 4 weeks of starting treatment and as clinically indicated thereafter. Discontinue treatment in patients who develop evidence of hepatic decompensation.
- A new contraindication was added for co-administration of Holkira Pak or Technivie with colchicine in patients with renal and/or hepatic impairment.

References

1. *Holkira Pak (ombitasvir/paritaprevir/ritonavir; and dasabuvir)* [product monograph]. St-Laurent (QC): AbbVie Corporation; 2016.
2. *Technivie (ombitasvir/paritaprevir/ritonavir)* [product monograph]. St-Laurent (QC): AbbVie Corporation; 2016.

* Relevant for Holkira Pak only; Technivie is not indicated for use in patients with cirrhosis.

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
- Canadian Drug Shortage Database

Suggestions?

Your comments are important to us. Let us know what you think by reaching us at InfoWatch_InfoVigilance@hc-sc.gc.ca

Health Canada
Marketed Health Products Directorate
Address Locator 0701D
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.: 150182
ISSN: 2368-8025