Health Canada Santé Canada

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

Health Product InfoWatch

August 2019

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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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HEALTH PRODUCTS MENTIONED IN THIS ISSUE

Pharmaceuticals and Biologics

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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

ANNOUNCEMENT

Educational Support for Mandatory Reporting of Serious Adverse Drug Reactions and Medical Device Incidents by Hospitals

New regulations requiring hospitals to report serious adverse drug reactions and medical device incidents to Health Canada will come into force on December 16, 2019. To support reporting and training activities in hospitals, 4 PowerPoint modules designed to raise awareness of mandatory reporting are available for download from the Canadian Patient Safety Institute webpage. These materials can be used (as entire modules, individual slides, or selected content) for individual learning or incorporated into presentations, orientation, continuing education, and other information-sharing activities.

Learn about what and how to report at: Canada.ca/drug-device-reporting.

For more information: hc.canada.vigilance.sc@canada.ca.
Phone: 1-866-234-2345 | Fax: 1-866-678-6789

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 2019 by Health Canada.

EpiPen (epinephrine) Information Update	While there has been stable supply of EpiPen auto-injectors in Canada in 2019 to date, a shortage of EpiPen (0.3 mg) auto-injector may lead to temporary supply constraints in the coming months. EpiPen Jr (0.15 mg) is not affected by this shortage. Based on information to date, Health Canada anticipates there will be adequate supply of epinephrine 0.3 mg auto-injectors in Canada to meet the needs of Canadians. The Interim Order that facilitates the import of an alternative epinephrine auto-injector (0.15 mg and 0.3 mg), Auvi-Q, remains in effect, and Auvi-Q remains accessible to Canadians.
Platelet Rich Plasma treatments Information Update	In follow-up to Health Canada's communication on unauthorized stem cell therapies on May 15, 2019, Health Canada informed Canadians and healthcare professionals that Platelet Rich Plasma treatments, including Platelet Rich Fibrin treatments, are not the same as cell therapies and, as a result, are not subject to Health Canada's Policy Position Paper on Autologous Cell Therapy Products.
Propofol-containing products Summary Safety Review	This safety review evaluated the risk of priapism associated with propofol-containing products. Health Canada's review concluded that there may be a link. Health Canada has been working with the manufacturers to update the Canadian product monographs for products containing propofol to include information about this potential risk.

Surgical mesh products Information Update Summary Safety Review	This safety review evaluated the risk of complications associated with non-absorbable synthetic surgical mesh for the transvaginal repair of pelvic organ prolapse (POP). Health Canada's safety review found that, compared to other treatment options, the transvaginal implantation of non-absorbable synthetic surgical mesh to treat posterior compartment prolapse poses a greater risk of complications. Health Canada's review also found that the use of non-absorbable synthetic mesh for the transvaginal surgical repair of anterior and/or apical prolapse should only be used for patients who have significant risk factors for recurrence of POP, patients that have recurrent POP, or for whom alternative surgical treatments are not appropriate. Health Canada is working with the manufacturer to remove synthetic surgical mesh devices indicated for the transvaginal repair of posterior compartment POP from the Canadian market. Health Canada has also communicated this safety information to Canadians.
Tacrolimus, oral formulations Health Professional Risk Communication	Graft rejection and other adverse reactions from either under- or over-exposure to tacrolimus have been reported due to inadvertent switching between oral tacrolimus formulations without appropriate dosing adjustments and monitoring. In order to prevent inadvertent switching, healthcare professionals are advised to add prominent descriptors for the different formulations when identifying tacrolimus products and to use brand/product names throughout the medication use process. Healthcare professionals have also been advised to consider an automated alert for computerized prescriber and pharmacy order entry that includes a warning that these formulations are not interchangeable, as well as a dosing frequency reminder.
U by Kotex Sleek and U by Kotex Click menstrual tampons Summary Safety Review	Health Canada's safety review evaluated the risk of tampon fraying during removal and subsequent potential adverse reactions. Health Canada's safety review concluded that the recall initiated by the manufacturer on December 11, 2018, for specific batches of U by Kotex Sleek tampons, addressed the observed increased reporting of tampon fraying for this product. The safety review also concluded that a recall of U by Kotex Click tampons is not necessary at this time. Health Canada will work with the manufacturer to ensure the effectiveness of the corrective measures taken to address the issue of tampon fraying in U by Kotex Sleek tampons during removal.
Unauthorized health products "Blackout" sleep-aid Infrared saunas Unauthorized eye solutions Update - Multiple unauthorized health 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 pharmaceuticals is available on Health Canada's Product Monograph Brand Safety Updates. Canadian product monographs can be accessed through Health Canada's Drug Product Database.

Cymbalta (duloxetine hydrochloride)

The risk of **postpartum hemorrhage** has been included in the *Warnings and Precautions* and *Patient Medication Information* sections of the Canadian product monograph for Cymbalta.

Key messages for healthcare professionals:[1]

- An observational study evaluating the risks of maternal outcomes associated with exposure to duloxetine during pregnancy demonstrated an increased risk of postpartum hemorrhage for women exposed to duloxetine.
- The risk of postpartum hemorrhage was 36/1000 (95% confidence interval: 24.8-49.4) in women exposed to duloxetine close to delivery (final 30 days of pregnancy) compared to 23/1000 (95% confidence interval: 23.1-23.4) in women who were not exposed to duloxetine during pregnancy (adjusted relative risk: 1.53 [95% confidence interval: 1.08-2.18]).
- When treating a pregnant woman, the use of duloxetine close to labour and delivery should only be considered if the potential benefit justifies the potential risk to the fetus and the mother.

Reference

1. *Cymbalta (duloxetine hydrochloride)* [product monograph]. Toronto (ON): Eli Lilly Canada Inc.; 2019.

Istodax (romidepsin)

The risk of romidepsin use in patients with **severe hepatic impairment** has been updated in the *Warnings and Precautions* (including the *Serious Warnings and Precautions* Box), *Dosage and Administration*, *Action and Clinical Pharmacology* and *Consumer Information* sections of the Canadian product monograph for Istodax.

Key messages for healthcare professionals:[1]

- Istodax is not recommended in patients with severe hepatic impairment, as the safe dose of romidepsin has not been established for this patient population.
- No dose adjustment is recommended for patients with mild hepatic impairment.
- If the benefit is considered to outweigh the risk in a patient with moderate hepatic impairment, a 50% reduction of the starting dose to 7 mg/m^2 is recommended.
- The risk of adverse effects associated with Istodax may be increased in patients with hepatic impairment. Patients should be monitored for signs of toxicity.

Reference

1. *Istodax (romidepsin)* [product monograph]. Mississauga (ON): Celgene Inc.; 2019.

HELPFUL LINKS

- MedEffect™ Canada
- Recalls and Safety Alerts Database
- New Safety and Effectiveness 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
- Annual trends for adverse reaction case reports and medical device problem incidents
- Stop Illegal Marketing of Drugs and Devices

Suggestions?

Your comments are important to us. Let us know what you think by reaching us at HC.infowatch-infovigilance.SC@canada.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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