Health Canada Santé Canada

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Health Product InfoWatch

March 2018

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REPORTING ADVERSE REACTIONS

Canada Vigilance Program
Online: Adverse Reaction and Medical Device Problem Reporting
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HEALTH PRODUCTS MENTIONED IN THIS ISSUE

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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

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 February 2018 by Health Canada.

Alysena 21 and 28 (levonorgestrel and ethinyl estradiol) Advisory - Alysena 28 Advisory - Alysena 21 and 28 Drug Recall	Apotex Inc. recalled one lot of Alysena 28 (lot LF10133A) after complaints about chipped pink pills in sealed blister packages. Pharmacists are reminded to check each blister pack of Alysena 28 before dispensing it to make sure the pills look as they should and to report any unusual pills to Apotex Inc. and to Health Canada. Since this recall, Health Canada informed Canadians that all lots of both Alysena 21 and Alysena 28 may have chipped pills.
Carbocaine 2% Drug Recall	Pfizer Canada Inc. has recalled Carbocaine 2% (lot 73100DD) as vials may be cracked in the affected lot.
Erwinase (Erwinia L-asparaginase) Health Professional Risk Communication	To help manage the impact of the ongoing shortage of Erwinase, some previously unreleased UK-labelled Erwinase vials are now being made available. These vials should be used with a standard 5-micron filter needle due to the presence of particulate matter. 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, do not administer the product and retain for collection. Healthcare professionals are reminded that there are some differences between the currently approved Canadian and UK labelling and should refer to the Erwinase Canadian product monograph for prescribing information.
Jakavi (ruxolitinib) Summary Safety Review	This safety review evaluated the risk of liver injury associated with Jakavi (ruxolitinib). Health Canada's review concluded that the evidence does not show a link between ruxolitinib and the risk of liver injury. The Canadian product monograph for the drug is appropriate at this time because it recommends that healthcare professionals test the patient's blood to check the liver before starting treatment with ruxolitinib and at regular periods afterward.
SGLT2 inhibitors Summary Safety Review	This safety review evaluated the risk of posterior reversible encephalopathy syndrome in patients treated with sodium-glucose cotransporter-2 (SGLT2) inhibitors (canagliflozin, dapagliflozin, empagliflozin) who had developed diabetic ketoacidosis. Health Canada's review of the available information did not find enough evidence to make a link. Health Canada encourages consumers and healthcare professionals to report any side effects related to the use of these health products.

Sisu natural health products Advisory	Sisu Inc. recalled numerous natural health products because the glass bottles that the products are packaged in may contain glass fragments. The packaging defect was caused by a manufacturing issue involving some of the 100 mL glass bottles used in the packaging of certain Sisu products beginning in October 2015 through March 2016.
Tecentriq (atezolizumab) Health Professional Risk Communication	Severe cases of myocarditis have been reported in patients being treated with Tecentriq (atezolizumab) in clinical trials. Healthcare professionals are advised to monitor patients receiving Tecentriq for signs and symptoms of myocarditis, withhold Tecentriq therapy in patients with Grade 2 myocarditis and permanently discontinue Tecentriq treatment in patients with Grade 3 or 4 myocarditis. The Canadian product monograph has been updated to include this new safety information.
Unauthorized health products 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.
Ventolin Diskus (salbutamol) Advisory Drug Recall	GlaxoSmithKline Inc. recalled one lot of Ventolin Diskus inhalers (lot 786G) because the products may not deliver the intended dose. Individuals who do not receive the intended dose may not be aware that the dose was not delivered.

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.

CASE REPORT

Recent Canadian or international cases are selected based on their seriousness, frequency of occurrence or the fact that the reactions are unexpected. Case Reports are considered suspicions and are presented to stimulate reporting of similar suspected adverse events.

Combined use of the EasyCare hospital bed and over-bed table - risk of patient entrapment

The safety of hospital beds has been closely monitored for over 20 years in Canada and several measures have been put in place to minimize the risk of patient entrapment.[1-6] Despite these efforts, patient entrapment with serious complications, including death, continues to be reported in Canada.

In August 2017, Health Canada received an incident report describing a patient death suspected of being associated with entrapment after the patient's neck was caught between a bed and an over-bed table. Investigation by the facility showed that certain over-bed tables ("C-shaped" base configuration) combined with the Joerns EasyCare bed create hazardous conditions in which the table can tip and become locked in place when the bed is lowered. If the bed is lowered while the base of the over-bed table is positioned underneath the bed in a specific alignment, the steel bars from the bed come into contact with the table's base, causing the table to tip (Figures 1 and 2). Once the table has tipped, the bed's steel bar continues to apply force to the table's base, making it difficult to bring the table to an upright position.

Final analysis of the incident by the manufacturer revealed that the bed functioned as intended and the root cause was identified as the table base causing an obstruction under the bed that was not cleared before lowering the bed. The user manual includes a warning regarding the importance of ensuring that the areas under and near the bed are free of people and obstructions before adjusting the bed.[7]

The facility's current approach to preventing this type of incident is to lock the patient's remote control of the bed when an over-bed table is in place above the bed.

Fig. 1: Steel bars from the bed in contact with the base of the table.

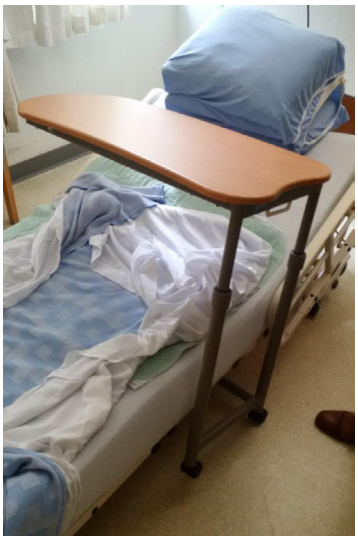

Fig. 2: Position of the bed when the patient was found deceased.

Although Health Canada has not received any other similar complaints, it is acknowledged that the same risk may exist for other bed models depending on the bed and table configuration. As for any type of device, it is recommended to properly follow the Instructions for Use provided with the medical device.

Any case of bed entrapment or other serious or unexpected adverse incidents in patients using hospital beds or side rails should be reported to Health Canada using the *Bed-related Entrapment and Fall Report Form*, available on Health Canada's Web site.

References

1. *Hospital Beds – Risk of Patient Entrapment - Dear Healthcare Professional Letter*. Ottawa (ON): Health Canada; 2017 Apr 7. (accessed 2018 Feb 12).
2. *Hospital bed safety*. Ottawa (ON): Health Canada; 2015 Feb 20. (accessed 2018 Feb 12).
3. *Hospital Beds – Risk of Patient Entrapment (Update) - Notice to Hospitals*. Ottawa (ON): Health Canada; 2012 Aug 10. (accessed 2018 Feb 12).
4. *Risk of Entrapment of Patients in Hospital Beds - Notice to Hospitals*. Ottawa (ON): Health Canada; 2009 Oct 20. (accessed 2018 Feb 12).
5. *Fact Sheet. Bed Rails In Hospitals, Nursing Homes and Home Health Care*. Ottawa (ON): Health Canada; 2008 June 26. (accessed 2018 Feb 12).
6. *Guidance Document. Adult Hospital Beds: Patient Entrapment Hazards, Side Rail Latching Reliability, and Other Hazards*. Ottawa (ON): Health Canada; 2008 Mar 17. (accessed 2018 Feb 12).
7. *EasyCare Bed* [User-Service Manual]. Arlington (TX): Joerns Healthcare LLC; 2015.

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

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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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