Health Canada Santé Canada

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Health Product InfoWatch

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REPORTING ADVERSE REACTIONS

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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 as well as summaries of completed safety reviews published in September 2015 by Health Canada.

Acetaminophen Information Update	Health Canada is seeking input on proposed revisions to strengthen the labelling standard for non-prescription acetaminophen products in order to help consumers use these products more safely. This consultation is one of several steps Health Canada is taking to further minimize the risk of liver damage and improve acetaminophen safety.
Becton-Dickinson disposable syringes Health Product Risk Communication	Certain lots of Becton-Dickinson (BD) general purpose disposable syringes with a specific type of stopper have been found to reduce the potency of some compounded or repackaged drugs stored in them. Compounded or repackaged drugs that have been stored in the affected lots of syringes should not be administered unless there is no suitable alternative available.
Gilenya (fingolimod) Information Update Summary Safety Review	This safety review evaluated the potential link between Gilenya (fingolimod) and neoplasms. Health Canada concluded that there was evidence of a potential link between Gilenya and an increased risk of lymphomas and other malignant cancers, particularly of the skin. The Canadian prescribing information for Gilenya has been updated to include this information. Health Canada has also communicated this risk (along with the risk of progressive multifocal leukoencephalopathy) to Canadians.
Humalog (insulin lispro) KwikPen 200 units/mL Health Product Risk Communication	Health Canada has recently authorized Humalog (insulin lispro) 200 units/mL KwikPen. Humalog (insulin lispro) 200 units/mL solution for injection should only be administered using the Humalog 200 units/mL KwikPen in which it is supplied. Transfer of the higher concentration insulin lispro 200 units/mL from the Humalog 200 units/mL KwikPen to a different insulin delivery system may lead to overdose and severe low blood sugar.
Octagam 5% and Octagam 10% (Immune Globulin Intravenous [Human]) Summary Safety Review	This safety review evaluated the potential lack of effectiveness associated with Octagam 5% and Octagam 10% (Immune Globulin Intravenous [Human]), as well as safety issues related to its manufacturing process, such as hypersensitivity and thromboembolic events. Health Canada did not find information linking Octagam 5% and Octagam 10% to a lack of effectiveness. Health Canada also found no evidence that the safety issues related to the manufacturing process ever posed a health risk to Canadians.

Remicade (infliximab) Summary Safety Review	This safety review evaluated the potential risk of developing three types of cancers (lymphoma, hepatosplenic T-cell lymphoma, and leukemia) when using Remicade (infliximab) to treat psoriasis in adults. Health Canada did not find evidence of an association between lymphoma, hepatosplenic T-cell lymphoma, or leukemia, and Remicade use. Health Canada will continue to monitor this issue.
Revolade (eltrombopag) Summary Safety Review	This safety review evaluated the potential risk of serious skin reactions associated with Revolade (eltrombopag). Health Canada concluded that the evidence did not support this link. Health Canada will continue to monitor adverse reaction information involving Revolade.
Unauthorized health products Information Update	Health Canada seized three unauthorized health products from Taste of Ukraine, in Burnaby, B.C. The products were labelled with prescription drug names (ampicillin, doxycycline and diclofenac). The seized products have not been approved by Health Canada.
Velcade (bortezomib) Summary Safety Review	This safety review evaluated the potential risk of necrotising fasciitis associated with Velcade (bortezomib). Health Canada could not establish a link due to limited evidence. Health Canada has requested additional information from the manufacturer and will continue to monitor this 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.

SAFETY BRIEF

Brilinta (ticagrelor) safety reminders

Brilinta (ticagrelor), in association with acetylsalicylic acid (ASA), is indicated for the secondary prevention of atherothrombotic events in patients with acute coronary syndromes.[1] It has been available in Canada since June 2011.

In an ongoing effort to ensure the safe and effective use of medications, Health Canada has reviewed 3 surveys of ticagrelor prescribers in Canada, which were conducted by the manufacturer. These surveys indicated that some prescribers did not present a full understanding of the appropriate ASA doses for co-administration with ticagrelor, as well as bleeding risks associated with the medication.

Health Canada would like to remind healthcare professionals of the following important safety and usage information related to bleeding that is in the Brilinta Canadian Product Monograph:[1]

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Safety reminders

Ticagrelor therapy should be initiated with a single 180 mg oral loading dose (two 90 mg tablets) and then continued at 90 mg twice daily.

Based on a relationship observed in the PLATO trial* between maintenance ASA dose and relative efficacy of ticagrelor compared to clopidogrel, ticagrelor is recommended to be co-administered with **low maintenance dose ASA** (75-150 mg daily). Co-administration of ticagrelor and high maintenance dose ASA (above 150 mg daily) is not recommended.

Patients taking ticagrelor should take ASA daily, unless specifically contraindicated.

Contraindications for ticagrelor include active pathological bleeding (such as peptic ulcer or intracranial hemorrhage) and a history of intracranial hemorrhage.

Ticagrelor should be used with caution in the following patient groups:

- Patients with a propensity to bleed (e.g., due to recent trauma, recent surgery, active or recent gastrointestinal bleeding, or moderate hepatic impairment).
- Patients requiring oral anticoagulants (e.g., warfarin) and/or fibrinolytic agents (within 24 hours of ticagrelor dosing).
- Patients with concomitant administration of medicinal products that may increase the risk of bleeding, such as non-steroidal anti-inflammatory drugs (NSAIDs).

Patients should not discontinue ticagrelor without first talking to their physician.

Healthcare professionals should be aware that Canadian product monographs (CPMs) are updated periodically as required. CPMs are available from the manufacturer or on the Health Canada Web site. Healthcare professionals are also encouraged to report to Health Canada any adverse reaction suspected of being associated with the use of ticagrelor.

Reference

1. *Brilinta (ticagrelor)* [product monograph]. Mississauga (ON): AstraZeneca Canada Inc.; 2014.

* Information on the PLATO trial is available on the U.S. National Institutes of Health's ClinicalTrials.gov Web site at https://clinicaltrials.gov/ct2/show/NCT00391872?term=PLATO&rank=1.

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

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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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