



Health
Canada

Santé
Canada

Your health and
safety... our priority.

Votre santé et votre
sécurité... notre priorité.



Health Product InfoWatch

January 2018

HEALTH PRODUCTS MENTIONED IN THIS ISSUE

CONTENTS

Announcement

- Consultation on naming of biologic drugs 2

Monthly recap 2

New information

- *Product monograph update:*
Ofev (nintedanib) 5

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](#).

Pharmaceuticals and Biologics

Alesse 21 and Alesse 28
 Anesthetic drugs
 Barbiturates
 Benzodiazepines
 Desflurane
 Gilenya (fingolimod)
 Isoflurane
 Ketamine
 Lorazepam
 Midazolam
 Ofev (nintedanib)
 Opioid drugs
 Phenobarbital
 Propofol
 Proton pump inhibitors (PPIs)
 Sedative drugs
 Sevoflurane
 Thiopental
 Zydelig (idelalisib)

Medical Devices

Fentanyl-detection test strips

Other

Foreign health products
 Unauthorized health products

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.

ANNOUNCEMENT

Consultation on naming of biologic drugs

Health Canada and the Institute for Safe Medication Practices Canada (ISMP Canada) are seeking input from healthcare providers, consumers, and other stakeholders on different approaches to the naming of biologic drugs, including biosimilars, in Canada.

Results of the [consultation](#) will be used to:

- understand the impact of different proposed approaches to biologic drug naming and the perspectives of stakeholders, and
- inform Health Canada's policy decision on a naming convention for biologic drugs.

The questionnaire and further details on this initiative can be accessed online from January 18 to February 9, 2018.

Please distribute this message to colleagues, members, or stakeholders to inform them of the consultation.

[Access the questionnaire](#)

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 December 2017 by Health Canada.

| | |
|---|---|
| Alesse 21 and Alesse 28 Health Professional Risk Communication Advisory | Blister packages for Alesse 21 and Alesse 28 were found to contain one broken pink tablet in a sealed blister. Broken or split birth control tablets may deliver a smaller dose of the active drug ingredients. Healthcare professionals are advised to remind patients to check tablets before taking them and not consume tablets that are broken or split; return blister packages containing broken or split tablets to the pharmacy to get a replacement package; and seek counsel on the proper use of oral contraceptives, and on what to do if a dose is missed. |
| Benzodiazepines and barbiturates Summary Safety Review Information Update | This safety review evaluated the risk of neurodevelopmental disorders associated with lorazepam, midazolam, phenobarbital and thiopental. Health Canada's review of the available information concluded that there is limited evidence suggesting a link between the use of these sedative and anesthetic drugs and neurodevelopmental disorders. Health Canada will look into working with the Drug Safety and Effectiveness Network to further study the link between the use of sedative and anesthetic drugs and the development of the brain. Health Canada has also communicated this information to Canadians. |

| | |
|--|--|
| <p>Fentanyl-detection test strips</p> <p>Information Update</p> | <p>Health Canada advised Canadians of the potential limitations when using test strips to detect fentanyl in street drugs. A preliminary study undertaken by Health Canada indicated that false negatives could occur when using fentanyl-detection test strips. A false negative could lead to a false sense of security which may result in overdose or death.</p> |
| <p>Foreign health products</p> <p>Foreign Product Alert</p> | <p>These foreign health products have been found by regulators in other countries to contain undeclared drug ingredients. The 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.</p> |
| <p>Gilenya (fingolimod)</p> <p>Summary Safety Review Health Product InfoWatch</p> | <p>This safety review evaluated the risk of thrombocytopenia associated with Gilenya (fingolimod). Health Canada's safety review established a potential link. The Canadian product monograph for Gilenya has been updated to inform about this potential safety issue. Health Canada has also communicated this information to healthcare professionals.</p> |
| <p>Opioid drugs</p> <p>Information Update</p> | <p>As part of the Government's action to reduce the harms of opioids, Health Canada held a Scientific Advisory Panel on Opioid Use and Contraindications to consider whether the current contraindications for opioid use are sufficient, or whether labelling updates and other actions may be needed to reduce risks to Canadians. After thoroughly assessing the Panel's recommendations, Health Canada is working with manufacturers to update the Canadian labelling of all prescription opioid products. Labelling updates include a recommendation for a daily opioid threshold dose for the management of chronic non-cancer, non-palliative pain; a recommendation to limit the quantity of opioids prescribed for acute pain; and clarification of warnings, including those for special populations such as pregnant women and patients with a history of dependence or substance use disorder.</p> |
| <p>Proton pump inhibitors (PPIs)</p> <p>Summary Safety Review</p> | <p>This safety review evaluated the risk of subacute cutaneous lupus erythematosus (SCLE) associated with proton pump inhibitors (PPIs). Health Canada's safety review concluded that there is a rare risk of SCLE associated with PPI use. Canadian product monographs for all PPI-containing products will be updated to inform healthcare professionals and patients.</p> |

Sedative and anesthetic drugs

[Summary Safety Review Information Update](#)

This safety review evaluated the risk of neurodevelopmental disorders associated with sedative and anesthetic drugs: desflurane, isoflurane, ketamine, propofol and sevoflurane. Health Canada's review concluded that repeated or lengthy use (more than 3 hours) of these sedative and anesthetic drugs in pregnancy and in children up to approximately 3 years of age may potentially lead to neurodevelopmental disorders in children. The Canadian product monographs of these drugs will be updated with warnings about this potential risk. Health Canada will also look into working with the [Drug Safety and Effectiveness Network](#) to further study the link between the use of sedative and anesthetic drugs and the development of the brain. Health Canada has also communicated this information to Canadians.

Unauthorized health products

Advisories:

[Multiple unauthorized drugs seized in Richmond, B.C.](#)

[Smart Brain Formulations Serotonin Support](#)

[Ultra Pure Colloidal Silver](#)

[Update - Products manufactured by Robert Lamberton Consulting, Cutting Edge Naturals and Cutting Edge Nutraceuticals](#)

[Update - Sexual enhancement 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.

Zydelig (idelalisib)

[Summary Safety Review](#)

This safety review evaluated the risk of progressive multifocal leukoencephalopathy (PML) associated with Zydelig (idelalisib). Health Canada's review concluded that there was a possible link. The Canadian product monograph will be updated to include a warning about 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.

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](#).

Ofev (nintedanib)

Additional information concerning the risk of **gastrointestinal perforation** has been added to the *Warnings and Precautions* section of the Canadian product monograph for Ofev (nintedanib).

Key messages for healthcare professionals:¹

- Cases of gastrointestinal perforations have been reported during the post-marketing period. Many of them were serious and some have resulted in fatal outcomes, although a definitive causal relationship to Ofev has not been established.
- Particular caution should be exercised when treating patients with previous abdominal surgery, a recent history of hollow organ perforation, previous history of peptic ulceration, diverticular disease, or receiving concomitant corticosteroids or non-steroidal anti-inflammatory drugs. Ofev should only be initiated at least 4 weeks after abdominal surgery.
- Only use Ofev in patients with a known risk of gastrointestinal perforation if the anticipated benefit outweighs the potential risk. Therapy with Ofev should be permanently discontinued in patients who develop gastrointestinal perforation.

Reference

1. *Ofev (nintedanib)* [product monograph]. Burlington (ON): Boehringer Ingelheim (Canada) Ltd.; 2017.

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

Health Canada
Marketed Health Products Directorate
Address Locator 1906C
Ottawa ON K1A 0K9
Telephone: 613-954-6522
Fax: 613-952-7738

Copyright

© 2018 Her Majesty the Queen in Right of Canada. This publication may be reproduced without permission provided the source is fully acknowledged. The use of this publication for advertising purposes is prohibited. Health Canada does not assume liability for the accuracy or authenticity of the information submitted in case reports.

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.: 170363
ISSN: 2368-8025
