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 December 2015 by Health Canada.

Avonex (interferon beta-1a) Summary Safety Review	This safety review evaluated the potential risk of thrombotic microangiopathy associated with the use of Avonex. Health Canada's review concluded that there is evidence of a potential link between Avonex and the risk of thrombotic microangiopathy. Health Canada has requested that the manufacturer update the Canadian prescribing information to include this risk. Health Canada will continue to monitor this issue.
Benzoyl peroxide or salicylic acid-containing topical acne products Summary Safety Review Information Update	This safety review evaluated the potential link between serious hypersensitivity reactions and over-the-counter topical acne products containing either benzoyl peroxide or salicylic acid. Health Canada concluded there was evidence supporting a link between the use of over-the-counter topical acne products containing either benzoyl peroxide or salicylic acid and serious hypersensitivity reactions. Health Canada will update the directions of use and warnings sections of the Health Canada Acne Therapy Monograph for these products. Health Canada has also communicated this information to Canadians.
Codeine-containing prescription products indicated for cough Summary Safety Review	This safety review further evaluated the risk of serious breathing problems in children and adolescents treated with codeine prescription products for cough. Health Canada maintains its warnings and recommendations to manage the risk of serious breathing problems and death, that codeine prescription products not be recommended in children less than 12 years of age. Health Canada will continue to monitor this issue.
Digital temple thermometers Information Update	Shoppers Drug Mart, in consultation with Health Canada, voluntarily recalled Life Brand Instant Read Digital Temple Thermometers (Model No. 057800711568), due to some devices displaying temperatures that are lower than actual body temperatures.
Finasteride Summary Safety Review Health Product InfoWatch	This safety review evaluated the potential risk of suicidality associated with the use of finasteride. Health Canada's review concluded that the evidence was too limited to determine whether or not a link between finasteride and suicidality exists. Health Canada will continue to monitor this issue. Health Canada has also communicated this information to healthcare professionals.
Gardasil (quadrivalent human papillomavirus [types 6, 11, 16, 18] recombinant vaccine) Summary Safety Review Information Update	This safety review evaluated the potential risk of autoimmune diseases and cardiovascular diseases associated with the use of Gardasil. Health Canada's review did not find any new safety issues concerning Gardasil. Health Canada has communicated this information to Canadians and will continue to monitor this issue. The safety of all vaccines, including Gardasil, is under continuous monitoring by Health Canada and the Public Health Agency of Canada.

Hospira health products Health Product Risk Communication	Fourteen health products manufactured by Hospira had incorrect, outdated or missing safety information on the inner/outer labels and/or package insert of certain lots. The labels on the products and/or the package inserts are being corrected as soon as possible to include the most updated information approved by Health Canada.
Melatonin (N-acetyl-5-methoxytryptamine) Summary Safety Review	This safety review evaluated the potential risk of neurological side effects associated with the use of melatonin in the pediatric population (newborn to 18 years old). Health Canada's review concluded that there is limited data about neurological side effects associated with the use of melatonin in the pediatric population. Health Canada will continue to monitor this issue.
System 83 Plus reprocessing devices Health Product Risk Communication	Reports of infection have been associated with the use of System 83 Plus reprocessing devices in the United States. An infection could result from inadequate reprocessing of complex endoscopes such as duodenoscopes with a closed elevator (lifter) channel. At this time, it is recommended not to use the System 83 Plus device to reprocess complex endoscopes and to use an alternative method.
Unauthorized health products Information Update	Health Canada seized five unauthorized drugs from retailers in British Columbia and Ontario. The products were labelled to contain prescription drugs, a narcotic or found to contain a prescription drug that was not listed on the label. The seized products have not been approved by Health Canada.
Unlicensed medical devices (Cryosaunas) Advisory	Health Canada advised Canadians that several clinics in Ontario and at least one in Québec are currently using illegally imported medical devices, Cryosaunas, which are potentially linked to a death in the US. Health Canada has requested that the manufacturer stop the sale and immediately recall the unlicensed medical devices.
Zelboraf (vemurafenib) Health Product Risk Communication	Cases of radiation sensitization and radiation recall reaction have been reported in patients treated with radiation prior to, during, or following Zelboraf (vemurafenib) treatment. It is recommended that Zelboraf not be used concomitantly with radiation therapy, unless the potential benefit justifies the potential risk. New warnings have been added to the Canadian prescribing information for Zelboraf advising of this serious 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.

Galexos (simeprevir)

The risk of hepatic decompensation and hepatic failure (including fatal cases) has been included in the Warnings and Precautions, Adverse Reactions, Dosage and Administration and Consumer Information sections of the Galexos Canadian product monograph. The Action and Clinical Pharmacology section has also been updated in relation to this issue.

Key messages for healthcare professionals:[1]

- Hepatic decompensation and hepatic failure (including fatal cases) have been reported in patients treated with Galexos (simeprevir) in combination with pegylated interferon (Peg-IFN) alfa and ribavirin (RBV) or in combination with sofosbuvir. Most cases were reported in patients with advanced and/or decompensated cirrhosis, who are at increased risk for hepatic decompensation or hepatic failure.
- Galexos is not recommended for use in patients with moderate or severe hepatic impairment (Child-Pugh Class B or C).
- Monitor liver chemistry tests before and as clinically indicated during Galexos combination therapy. Patients who experience an increase in total bilirubin greater than 2.5 times the upper limit of normal should be closely monitored.
- Discontinue Galexos if elevation in bilirubin is accompanied by clinically relevant liver transaminase increases or clinical signs and symptoms of hepatic decompensation.

Reference

1. *Galexos (simeprevir)* [product monograph]. Toronto (ON): Janssen Inc.; 2015.

Optiray (ioversol)

The risk of hypothyroidism in infants has been included in the Precautions and Adverse Reaction sections of the Optiray Canadian product monograph.

Key messages for healthcare professionals:[1]

- Optiray, like all other iodinated contrast media (ICM), may induce changes in thyroid function in some patients, including enhancement or suppression of thyroid function.
- Hypothyroid status in infants, especially premature infants, has been shown to remain for weeks or even more than a month following ICM administration.
- Hypothyroidism during the neonatal period may be harmful for growth and development, including mental development.

Reference

1. *Optiray (ioversol)* [product monograph]. Pointe-Claire (QC): Liebel-Flarsheim Canada Inc.; 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
- 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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