



Health Product InfoWatch

June 2015

HEALTH PRODUCTS MENTIONED IN THIS ISSUE

Pharmaceuticals and Biologics

Alveda Epinephrine Injection
Alveda Furosemide Injection
NaturaLyte Sodium Bicarbonate Liquid Concentrate
Nexavar (sorafenib)
Prolia (denosumab)
Sevorane AF (sevoflurane)
Uloric (febuxostat)

Natural Health Product

Galenic Health Ginger in Bentonite

Other

Foreign Health Products
Stiff Rock

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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.

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 May 2015 by Health Canada.

Alveda Furosemide Injection (USP 10 mg/mL)

[Health Product Risk Communication](#)

Alveda Pharmaceuticals Inc. recalled one lot (lot 30208) of Furosemide Injection USP 10 mg/mL which has the same barcode on its inner label as that of Alveda Epinephrine Injection USP 1 mg/mL. This could result in a serious medication error due to misidentification of either product leading to inadvertent administration of the wrong product.

Foreign Health Products

[Foreign Product Alert \(25 foreign products\)](#)

[Foreign Product Alert \(12 foreign products\)](#)

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.

Galenic Health Ginger in Bentonite

[Information Update](#)

Alliance Principle Ingredients/Neutrical Solutions Inc. recalled the natural health product Galenic Health Ginger in Bentonite (NPN 80053535) due to unacceptable levels of lead for adolescents and children. The product currently contains levels of lead beyond permitted limits for children, but within acceptable limits for adult dosing. Ginger in Bentonite is used to relieve digestive upset and disturbances.

NaturaLyte Sodium Bicarbonate Liquid Concentrate

[Health Product Risk Communication](#)

Fresenius Medical Care voluntarily recalled specific lots of NaturaLyte Sodium Bicarbonate Liquid Concentrate (DIN 02230083) in 6.4 L and 8 L volumes due to possible bacterial contamination.

Nexavar (sorafenib)

[Summary Safety Review](#)

This safety review evaluated the potential risk of drug-induced thyroid gland dysfunction associated with Nexavar (sorafenib). Health Canada concluded that there was evidence of thyroid gland disorders in association with Nexavar use. Health Canada has updated the Canadian prescribing information for Nexavar to inform healthcare professionals, caregivers and patients about the risks of thyroid dysfunction. Thyroid function monitoring should be considered before and during Nexavar use.

Prolia (denosumab)

[Summary Safety Review](#)

This safety review evaluated the potential risk of cardiovascular adverse events associated with the use of Prolia (denosumab). The current available evidence does not support an association between Prolia and the risk of cardiovascular adverse events. In addition, the risk of hypocalcemia and its effects on heart rhythm (e.g., QT interval prolongation) is included in the Canadian prescribing information.

<p>Sevorane AF (sevoflurane) Summary Safety Review</p>	<p>This safety review evaluated the potential risk of severe bradycardia with the use of the general anaesthetic sevoflurane (Sevorane AF and generics) in children with Down syndrome. Health Canada concluded that the risk of bradycardia with sevoflurane should be considered for all children. The prescribing information for sevoflurane mentions the risk of bradycardia in healthy children and in children with neuromuscular problems. This will now be updated to include the occurrence of cases of bradycardia in children with Down syndrome.</p>
<p>Stiff Rock Advisory</p>	<p>Health Canada testing found that the unauthorized health product “Stiff Rock” contains the undeclared drug ingredients sildenafil, aminotadalafil and hydroxythiohomosildenafil. The product, promoted for male sexual performance enhancement, was removed from sale from Boutique Érotique 5ieme avenue (also known as Boutique Érotique Liberté), in Valleyfield, QC.</p>
<p>Uloric (febuxostat) Summary Safety Review</p>	<p>This safety review evaluated the potential risk of agranulocytosis associated with Uloric (febuxostat). International cases of agranulocytosis suspected of being associated with the use of Uloric have been identified. Health Canada has not received any adverse reaction reports related to this issue. Health Canada has requested that the manufacturer submit information updates on the safety of Uloric which will be monitored and assessed.</p>

HELPFUL LINKS

- [MedEffect™ Canada](#)
- [Recalls and Safety Alerts Database](#)
- [Summary Safety Reviews](#)
- [New Safety Reviews](#)
- [Canada Vigilance Adverse Reaction Online Database](#)
- [Drug Product Database](#)
- [Canadian Drug Shortage Database](#)
- [The Drug and Health Product Register](#)

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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