



Health
Canada

Santé
Canada

Your health and
safety... our priority.

Votre santé et votre
sécurité... notre priorité.



Health Product InfoWatch

April 2016

HEALTH PRODUCTS MENTIONED IN THIS ISSUE

Pharmaceuticals and Biologics

- Bcr-Abl Tyrosine Kinase Inhibitors
- Cough and cold medication
- Gleevec and generics (imatinib mesylate)
- Personnelle sunscreen lotion
- Zydelig (idelalisib)

Natural Health Products

- Durazest for Men Volume
- Forta for Men Daily
- Forta Xpload
- Jamp-Hydrocortisone Cream 1%

Other

- Foreign health products
- Unauthorized health products (13 products)
- Unauthorized health products (6 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.

CONTENTS

Monthly recap 2

REPORTING ADVERSE REACTIONS

Canada Vigilance Program
Telephone: 1-866-234-2345
Fax: 1-866-678-6789
Online: www.health.gc.ca/medeffect

SUBSCRIBE

To receive the Health Product InfoWatch and notifications of health product advisories by email, subscribe to MedEffect™ e-Notice at www.health.gc.ca/medeffect

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 March 2016 by Health Canada.

Bcr-Abl Tyrosine Kinase Inhibitors

[Summary Safety Review](#)

This safety review assessed the risk of fetal harm when Bcr-Abl tyrosine kinase inhibitors are used by either parent (father or mother). Further to Health Canada's safety review, the manufacturer has updated the prescribing information for Gleevec to tell doctors to confirm by pregnancy test that female patients are not pregnant before starting treatment. No modifications were recommended for the prescribing information of the other tyrosine kinase inhibitors at this point in time.

Cough and cold medication

[Information Update](#)

Health Canada reminded Canadians that over-the-counter cough and cold medicines should not be given to children under the age of 6.

Foreign health products

[Foreign Product Alert \(27 products\)](#)

[Foreign Product Alert \(22 products\)](#)

[Foreign Product Alert \(11 products\)](#)

[Foreign Product Alert \(17 products\)](#)

These foreign health products have been found by regulators in other countries to contain undeclared drug ingredients or high levels of heavy metals. 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.

Forta for Men Daily, Forta Xpload and Durazest for Men Volume

[Advisory](#)

Vivo Brand Management Inc. has recalled additional natural health products promoted for sexual enhancement: "Forta for Men Daily", "Forta Xpload" and "Durazest for Men Volume". These products may contain an undeclared drug: sildenafil.

Gleevec and generics (imatinib mesylate)

[Summary Safety Review](#)

This safety review evaluated the risk of decline in kidney function linked with long-term treatment with imatinib. Health Canada's review concluded that there is sufficient evidence to consider a potential causal link between imatinib and decline in kidney function during long-term treatment. Health Canada is working with the manufacturer of Gleevec to include additional safety information on this risk into the Canadian Product Monograph.

<p>Jamp-Hydrocortisone Cream 1%</p> <p>Information Update</p>	<p>Jamp Pharma has recalled Jamp-Hydrocortisone Cream 1% (NPN 80057189), due to microbial contamination with bacteria, yeast and mould.</p>
<p>Personnelle sunscreen lotion</p> <p>Information Update</p>	<p>One lot of Personnelle sunscreen lotion (DIN 02395975) was recalled because of microbial contamination. The affected sunscreen was sold at Jean Coutu retail locations.</p>
<p>Unauthorized health products (13 products)</p> <p>Advisory</p>	<p>Health Canada seized 13 unauthorized drugs promoted for sexual enhancement or as bodybuilding supplements from 4 separate retailers in Ontario. The products were found to contain or were labelled to contain various prescription drug substances and other drug substances that may pose serious risks to the health of Canadians.</p>
<p>Unauthorized health products (6 products)</p> <p>Advisory</p>	<p>Health Canada seized 6 unauthorized products being promoted as dietary supplements from Herc's Nutrition in Brampton, Ontario. These products may pose serious risks to the health of Canadians.</p>
<p>Zydelig (idelalisib)</p> <p>Information Update</p>	<p>Four Canadian clinical trials, involving Zydelig (idelalisib) in combination with other anticancer drugs, were stopped after reports of an increased rate of serious adverse events, including deaths. Three additional trials will be amended by implementing added measures to protect participants.</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](#)
- [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

Health Canada
Marketed Health Products Directorate
Address Locator 0701D
Ottawa ON K1A 0K9
Telephone: 613-954-6522
Fax: 613-952-7738

Copyright

© 2016 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.: 150182
ISSN: 2368-8025*
