Health Canada Santé Canada

Your health and safety… our priority. *Votre santé et votre sécurité… notre priorité.*

Health Product InfoWatch

November 2020

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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

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To receive the Health Product InfoWatch and notifications of health product advisories electronically, subscribe to MedEffect™ e-Notice or to MedEffect™ Canada RSS feeds.

HEALTH PRODUCTS MENTIONED IN THIS ISSUE

Pharmaceuticals and Biologics

- Benzodiazepines and benzodiazepine-like prescription drugs
- Brilinta (ticagrelor)
- Codeine phosphate syrup
- GUM Paroex
- Non-steroidal anti-inflammatory drugs
- Picato (ingenol mebutate gel)
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Natural and Non-prescription Health Products

- Benzocaine
- Daily Shield Hand Sanitizers
- Hand sanitizers that may pose health risks
- Non-steroidal anti-inflammatory drugs

Other

- Counterfeit Zytec Germ Buster Hand Sanitizer
- Unauthorized health products

CORONAVIRUS DISEASE (COVID-19)

For the most up-to-date information on COVID-19, please visit the Government of Canada Coronavirus disease (COVID-19) website **Canada.ca/coronavirus**, which includes a dedicated section for healthcare professionals and for the health product industry.

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.

Health Product InfoWatch 2015 - 2020 5 years

Canada

MONTHLY RECAP OF HEALTH PRODUCT SAFETY INFORMATION

The following is a list of health product advisories, type I recalls and summaries of completed safety reviews published in October 2020 by Health Canada.

Benzocaine Health Professional Risk Communication Advisory	Benzocaine has been associated with the risk of methemoglobinemia. Health Canada communicated on this safety issue in 2012, 2011 and 2006. Despite these previous warnings concerning this risk, Health Canada is concerned that children under 2 years of age may still be given benzocaine products, given its history of use as a teething pain reliever. Healthcare professionals are reminded to NOT recommend benzocaine-containing products for children under 2 years of age. Health Canada has also communicated this information to Canadians.
Benzodiazepines and benzodiazepine-like prescription drugs Advisory	Health Canada is working with market authorization holders to update the safety labelling for benzodiazepines and benzodiazepine-like prescription drugs to provide patients and healthcare professionals with prominent and consistent messaging about severe and potentially life-threatening risks associated with these drugs. The update requested by Health Canada is related to the risks of problematic use and substance use disorder; severe withdrawal symptoms; harm when taken with opioids, which may cause deep drowsiness, respiratory depression, coma and death; and falls and fractures in specified populations.
Brilinta (ticagrelor) Summary Safety Review	This safety review evaluated the risk of central sleep apnea associated with Brilinta use. Health Canada's review concluded that there may be a link. Health Canada has requested that the manufacturer update the Canadian product monograph for Brilinta to add a warning about this potential safety issue.
Certain hand sanitizers that may pose health risks Advisory	Health Canada advised Canadians that certain hand sanitizers were recalled because they either contain ingredients that are not permitted by Health Canada or are not properly labelled and are missing important information.
Codeine phosphate syrup 5 mg/mL Advisory Drug Recall	Laboratoire Atlas Inc. recalled lot number 35MC of ATLAS - Codeine phosphate syrup, 5 mg/mL, (DIN 00050024) because some bottles contained isopropyl rubbing alcohol 70% instead of codeine syrup. This is the result of a labelling error during the packaging process where isopropyl rubbing alcohol products were mistakenly labelled as Codeine phosphate syrup, 5 mg/mL.
Counterfeit Zytec Germ Buster Hand Sanitizer Advisory	The distributor Northern National Sales Inc. recalled a counterfeit version of Zytec Germ Buster Hand Sanitizer 1L (labelled with NPN 80015625, lot number 3329733126).

Daily Shield Hand Sanitizers Advisory	Bio Life Sciences Corp. recalled all Daily Shield hand sanitizers from retail locations across Canada. Testing of Daily Shield hand sanitizer confirmed the presence of methanol, which is not authorized for use in hand sanitizers and can cause serious health issues. Frequent use of hand sanitizer containing methanol may cause dermatitis, eye irritation, upper respiratory system irritation and headaches. If ingested, methanol can cause severe, even deadly adverse reactions.
GUM Paroex Advisory Drug Recall	Sunstar Americas, Inc. recalled 5 lots of prescription anti-gingivitis oral rinse, GUM Paroex, after testing revealed the presence of *Burkholderia lata. Burkholderia lata* is a multi-drug-resistant bacteria that has a high potential to cause serious respiratory and other infections in patients with underlying illnesses, such as cystic fibrosis and chronic granulomatous disease or who are immunocompromised.
Non-steroidal anti-inflammatory drugs Advisory	Health Canada is investigating the use of non-steroidal anti-inflammatory drugs at 20 weeks or later in pregnancy and the rare, but serious, risk of kidney problems in an unborn baby that can lead to low levels of amniotic fluid and possible complications, in response to a Drug Safety Communication recently released by the U.S. Food and Drug Administration on this issue.
Picato (ingenol mebutate gel, 0.015% and 0.05%) Health Professional Risk Communication Information Update Drug Recall	Health Canada conducted a safety review of Picato and concluded that there may be a link between its use and an increased risk of non-melanoma skin cancer. Due to the unfavourable benefit-risk profile, the manufacturer withdrew Picato from the Canadian market at Health Canada's request. Health Canada has also communicated this information to Canadians.
Unauthorized health products Regener-Eyes Ophthalmic Solution and Regener-Eyes Ophthalmic Solution Lite Various unauthorized health 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.

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 pharmaceuticals is available on Health Canada's Product monograph brand safety updates page. Canadian product monographs can be accessed through Health Canada's Drug Product Database.

Zofran and Zofran ODT (Oral Disintegrating Tablets) (ondansetron)

The *Warnings and Precautions* and *Consumer Information* sections of the Canadian product monograph for Zofran and Zofran ODT have been updated with new safety information concerning the **risks during pregnancy**.

Key messages for healthcare professionals:[1]

- The use of ondansetron in pregnancy is not recommended.
- Ondansetron use during early pregnancy has been associated with a small increase in orofacial malformations. Despite some limitations in methodology, several human epidemiological studies noted an increase in orofacial clefts in infants of women administered ondansetron during the first trimester of pregnancy.
- Regarding cardiac malformations, the epidemiological studies showed conflicting results.

Reference

1. *Zofran and Zofran ODT (Oral Disintegrating Tablets) (ondansetron)* [product monograph]. Dorval (QC): Novartis Pharmaceuticals Canada Inc.; 2020.

HELPFUL LINKS

- MedEffect™ Canada
- Recalls and Safety Alerts Database
- New Safety and Effectiveness 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
- Stop Illegal Marketing of Drugs and Devices
- List of Drugs for Exceptional Importation and Sale

Suggestions?

Your comments are important to us. Let us know what you think by reaching us at HC.infowatch-infovigilance.SC@canada.ca

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

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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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