Health Canada Santé Canada

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Health Product InfoWatch

May 2020

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REPORTING ADVERSE REACTIONS

Canada Vigilance Program
Online: Adverse Reaction and Medical Device Problem Reporting
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HEALTH PRODUCTS MENTIONED IN THIS ISSUE

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Natural and Non-prescription Health Products

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- Homemade hand sanitizers

Other

- Fraudulent N95 respirators

CORONAVIRUS DISEASE (COVID-19)

For the most up-to-date information on COVID-19, please visit the Government of Canada Coronavirus disease (COVID-19) Web site **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

ANNOUNCEMENT

Labelling error for WinRho SDF (Rh_o(D) Immune Globulin (Human) for Injection)

A labelling error was identified in the *Patient Medication Information* section of the French Canadian product monograph and the French language product insert for WinRho SDF.[1] This error affects all marketed strengths of WinRho SDF, namely the 120 µg, 300 µg and 1000 µg strengths.

Under the section *Proper Use of This Medication*, the unit "g" for grams is present instead of the correct unit "µg" for micrograms. The dosage is also incorrect in the subsequent paragraph, where "1300 µg" is present instead of the correct dose of "300 µg". All other product information and dosing guidelines are correct.

Saol Therapeutics, the manufacturer, communicated this information to its customers. This information is available on the Canadian Blood Services and on the Héma-Québec (in French only) Web sites.

Reference

1. *WinRho SDF (Rh_o(D) Immune Globulin (Human) for Injection)* [product monograph]. Dublin (Ireland): Saol Therapeutics Research Limited; 2018.

Did you know?

List of Drugs for Exceptional Importation and Sale

Due to an unprecedented demand and urgent need for access to drugs during the COVID-19 pandemic, the Minister of Health signed an Interim Order to allow certain foreign drugs, approved by another regulator and with similar high quality and manufacturing standards to those required for Canadian approved products, to be imported and sold in Canada. An Interim Order is one of the fastest mechanisms available to address large-scale public health emergencies, without following the usual regulatory processes.

To access the list of these designated drugs please visit the List of Drugs for Exceptional Importation and Sale. The list is continuously updated as new foreign drug products are allowed to be imported.

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 April 2020 by Health Canada.

Chloroquine and hydroxychloroquine Information Update	Chloroquine and hydroxychloroquine may cause serious side effects, including serious heart rhythm problems. The risk of these side effects may increase at higher doses, or if the drugs are used in combination with other drugs, such as azithromycin. Patients should use these drugs only under the supervision of a physician. Health Canada is concerned that some people may be directly buying and using chloroquine and hydroxychloroquine to prevent or treat COVID-19 without a prescription. Health Canada has not authorized any drugs to prevent, treat or cure COVID-19 and has warned Canadians about products making false and misleading claims.

Direct-acting antivirals Summary Safety Review	This safety review evaluated the risk of new or returning hepatocellular carcinoma (HCC) associated with direct-acting antivirals (DAAs). This was a follow-up to the previous review completed in 2017, which examined the use of DAAs and the risk of HCC. This review was triggered by newly reported Canadian cases and new evidence from published scientific literature. Health Canada's review concluded that the available information did not support a link between the use of DAAs and new or returning HCC.
Fraudulent N95 respirators Advisory	Health Canada received reports that fraudulent and uncertified N95 respirators that falsely claim to protect consumers against COVID-19 are being illegally sold to consumers online and in some retail stores. In Canada, N95 respirators are regulated by Health Canada as Class I medical devices and are manufactured or imported by companies that hold a Medical Device Establishment Licence. They are also certified by the U.S. National Institute for Occupational Safety and Health (NIOSH). Fraudulent or unauthorized N95 masks may not meet the same performance measures required by the NIOSH N95 standard and, as a result, may not properly protect consumers from COVID-19.
Hand sanitizer products made with technical-grade ethanol Advisory	Hand sanitizers are normally made with Pharmacopeial (e.g., USP) or food grade ethanol. However, to address the shortage of hand sanitizer products during the COVID-19 pandemic, Health Canada is allowing, on a case-by-case basis and under specific conditions, the production of technical grade ethanol until June 30, 2020 and the manufacture of hand sanitizer products using this authorized technical grade ethanol until September 30, 2020. Based on Health Canada's risk assessment summary report some additional labelling is required for hand sanitizers containing technical grade ethanol, including that these products are intended for adult use only, they should not be used on broken or damaged skin, they should not be used by women who are pregnant or breastfeeding, and they should not be inhaled.
Hemlibra (emicizumab injection) Health Professional Risk Communication	COVID-19 is caused by a novel coronavirus, therefore its effects on people with Hemophilia A is not well understood. Patients with severe COVID-19 infection, with or without hemophilia, may develop a COVID-19 associated coagulopathy resembling disseminated intravascular coagulation (DIC) as the condition progresses. Hemlibra is known to interfere with one-stage clotting assays, some of which are used to diagnose and monitor patients with DIC. The communication includes a table which lists common coagulation assays that may be used to diagnose, monitor and manage patients with COVID-19 associated coagulopathy, and indicates whether these assays are affected by Hemlibra, and potential alternatives where applicable.

Homemade hand sanitizers Advisory	Health Canada warned Canadians about the potential health risks of making and using homemade hand sanitizers, as homemade recipes and products are becoming increasingly common online. The concentration of alcohol in many of the homemade hand sanitizers may not be high enough to kill the coronavirus that causes COVID-19. Homemade formulas may also present other health risks, such as skin irritation, increased sensitivity or allergies. Health Canada recommends only using hand sanitizers that have been authorized for sale in Canada. Product labels for authorized hand sanitizers will have either a Natural Product Number (NPN) or Drug Identification Number (DIN).
Methimazole Summary Safety Review	This safety review evaluated the risk of vasculitis associated with methimazole. Health Canada's review of the available information concluded that there is a link between the risk of vasculitis and the use of methimazole. Health Canada is working with manufacturers to update the Canadian product monographs of all methimazole products to include information about this potential risk.
Neuromuscular blocker (NMB) products Health Professional Risk Communications: Pancuronium Bromide Injection Quelicin (succinylcholine chloride injection) Rocuronium Bromide Injection Vecuronium Bromide Injection	There is an increased demand and shortage of neuromuscular blocker (NMB) products in Canada as a result of the COVID-19 pandemic. Health Canada has permitted the exceptional importation and sale of these US-labelled products to mitigate shortages of NMB products in Canada. Healthcare professionals should be aware of the labelling differences between the Canadian and US-labelled products, as well as the potential risk of errors resulting from inadvertent selection and administration of NMBs, resulting in serious harm to patients.
Salbutamol inhalers Advisory	Some manufacturers have reported shortages of salbutamol inhalers because of an increase in demand related to the current COVID-19 pandemic. At this time, to manage and conserve supply, most patients will receive only one inhaler at a time when they go to refill their prescription. Health Canada is working closely with other federal departments, provincial and territorial governments, international partners, and industry to help minimize the impact of this shortage and to help ensure that Canadians have access to the drugs they need during the COVID-19 pandemic. In addition, on March 30, 2020, the Minister of Health signed an Interim Order permitting the exceptional importation and sale of drugs needed to prevent or alleviate the effects of shortages directly or indirectly related to COVID-19.

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. Canadian product monographs can be accessed through Health Canada's Drug Product Database.

Tygacil (tigecycline)

The risk of **hypofibrinogenemia** and recommendations on monitoring of blood coagulation parameters have been included in the *Warnings and Precautions* and *Adverse Reactions (Post Marketing Adverse Reactions)* sections of the Canadian product monograph for Tygacil.

Key messages for healthcare professionals:[1]

- Physicians should monitor for blood coagulation parameters, including blood fibrinogen prior to treatment initiation with tigecycline and regularly while on treatment.

Reference

1. *Tygacil (tigecycline)* [product monograph]. Kirkland (QC): Pifzer 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
- Annual trends for adverse reaction case reports and medical device problem incidents
- Stop Illegal Marketing of Drugs and Devices

Suggestions?

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