Important Safety Information Importation of US-Labelled QUELICIN (succinylcholine chloride injection) due to Shortage of Canadian-labelled QUELICIN



Date 2020/04/29

Audience

Healthcare professionals including pharmacists, anesthesiologists, critical care physicians, emergency physicians and those involved with administering anesthesia or intubating patients.

Key messages

- There is an unprecedented demand and product shortage of the paralyzing agent QUELICIN (succinylcholine chloride injection USP) in Canada as a result of the COVID-19 pandemic.
- Given the medical necessity of this product, Health Canada has added QUELICIN (succinylcholine chloride injection USP) 200 mg/10 mL (20 mg/mL) vials to the List of Drugs for Exceptional Import and Sale.
- The US-labelled product should be used in the same manner as the Canadian product. Health care professionals should visit www.pfizer.ca/quelicin-succinylcholine-chloride-injection-usp to access the current Prescribing Information.
- The US-labelled product is identical to the Canadian-labelled product, in terms of the actual drug product content and volume of the vial. There are however differences in the labelling of the vials. An example of the vial labels (image) from both the US and Canada is provided in Appendix A.

What is the issue?

There is an unprecedented demand and shortage of QUELICIN (succinylcholine chloride injection USP) as a result of the COVID-19 pandemic. A limited quantity of US-labelled QUELICIN (succinylcholine chloride injection USP) 200 mg/10 mL (20 mg/mL) vials in a 10 mL format will be made available for Canadian patients.

Products affected

Pfizer Canada ULC, QUELICIN (succinylcholine chloride injection USP) 200 mg/10 mL (20 mg/mL) vials in a 10 mL format

Background information

QUELICIN (Succinylcholine chloride injection USP) is a medically necessary product, indicated as an adjunct to general anesthesia, to facilitate tracheal intubation, and to provide skeletal muscle relaxation during surgery or mechanical ventilation.

Information for healthcare professionals

This drug should be administered by appropriately trained healthcare professionals familiar with its actions, characteristics, and hazards.

The US-labelled product is identical to the Canadian-labelled product, in terms of the actual drug product content and container closure (red cap with "Paralyzing Agent" in white ink). The US-labelled product should be used in the same manner as the Canadian product.

There are differences in the labelling of the vials and cartons. A comparison of the US and Canadian vial labels is provided below in **Appendix A**.

Health Canada is aware of domestic and international reports of neuromuscular blockers being used in error resulting in serious patient harm, including death; some of these errors are related to differences in the labelling and packaging of these products.

Health care professionals should visit https://www.pfizer.ca/quelicin-succinylcholine-chloride-injection-usp to access the current Prescribing Information.

Action taken by Health Canada

The Minister of Health signed the <u>Interim Order Respecting Drugs, Medical Devices</u> and Foods for a Special Dietary Purpose in relation to COVID-19 (https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/covid19-interim-order-drugs-medical-devices-special-foods/information-provisions-related-drugs-biocides/list.html). Drugs included on the <u>List of Drugs for Exceptional Importation and Sale</u> referenced in the Interim Order are eligible for the exceptional importation and sale provisions provided for in the Interim Order. Health Canada has added QUELICIN to this list, which permits the importation and sale of US-labelled QUELICIN.

Health Canada has worked with Pfizer Canada ULC to prepare this alert for Succinylcholine chloride injection. Health Canada is communicating this important safety information to healthcare professionals and Canadians via the <u>Recalls and Safety Alerts Database on the Healthy Canadians Web Site</u> (https://healthycanadians.gc.ca/recall-alert-rappel-avis/index-eng.php). This communication update will be further distributed through the MedEffect™ e-Notice email notification system, as well as through social media channels, including LinkedIn and Twitter.

Report health or safety concerns

Managing marketed health product-related side effects depends on health care professionals and consumers reporting them. Any case of serious or unexpected side effects in patients receiving QUELICIN should be reported to Pfizer Canada ULC or Health Canada.

Pfizer Canada ULC 17300 Trans-Canada Highway Kirkland, QC H9J 2M5

Telephone: 1-866-723-7111 Fax: 1-855-242-5652

To correct your mailing address or fax number, contact Pfizer Canada ULC.

You can report any suspected adverse reactions associated with the use of health products to Health Canada by:

- Calling toll-free at 1-866-234-2345; or
- Visiting MedEffect Canada's Web page on <u>Adverse Reaction Reporting</u> (http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php) for information on how to report online, by mail or by fax.

For other health product inquiries related to this communication, contact Health Canada at:

Marketed Health Product Directorate E-mail: hc.mhpd-dpsc.sc@canada.ca

Telephone: 613-954-6522 Fax: 613-952-7738

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Sincerely,

Vratislav Hadrava M.D., Ph.D. Vice President & Medical Director

Pfizer Canada ULC

Appendix A - Comparison of the US and Canadian vial labels

COMPARISON OF VIAL LABELS	
<u>US vial label</u>	Canadian vial label
To mL SUCCINYLCHOLINE SUCCINYLCHOLINE CHLORIDE INJECTION, USP 200 mg/10 mL (20 mg/mL) WARNING: Paralyzing Agent OUELICIN™ WARNING: Paralyzing Agent WARNING: Paralyzing Agent Cuelicin Mary Company Agent Ouelicin Mar	10 mL Nº 06629 DIN 00038172 Multidose Sterile Solution stérile Quelicin® Succinylcholine chloride injection USP 200 mg/10 mL (20 mg/mL) For I.V. Use / Pour administration i.v. PARALYZING AGENT/AGENT PARALYSANT NEUROMUSCULAR BLOCKING AGENT Also contains: 2 mg/mL parabens (as preservatives). Storage: Refrigerate (2 to 8°C). AGENT DE BLOCAGE REUROMUSCULAIRE Contient aussi: 2 mg/mL de parabènes (comme préservateurs). Entre- posage: réfrigérer (2 à 8°C). RI-6750 Pizer Canada Inc. Kirkland (Québec) H9J 2M5
English only	English and French
10 mL SUCCINYLCHOLINE Chloride Injection, USP 200 mg/10 mL (20 mg/mL) QUELICIN™	10 mL PrQuelicin® Succinylcholine chloride injection USP 200 mg/10 mL (20 mg/mL)
WARNING: Paralyzing Agent. Causes Respiratory Arrest. Facilities must be immediately available for artificial respiration.	PARALYZING AGENT
NDC 0409-6629-12	DIN 00038172
RL-7211	RL-6750
No commodity No	Nº 06629
Multiple-dose	Multidose
Sterile, nonpyrogenic For Intravenous or Intramuscular use.	Sterile Solution, does not indicate 'nonpyrogenic'
For intravenous of intramuscular use.	For I.V. Use, Intramuscular use is not added on the label but is included in the leaflet (infants,
	older children or adults, if necessary)
Does not indicate Therapeutic Classification	NEUROMUSCULAR BLOCKING AGENT
Also contains 0.18% methylparaben and 0.02%	Also contains 2mg/mL parabens (as preservatives)
propylparaben added as preservatives.	(az p. 336, 746, 756)
Store at 2° to 8°C	Storage: Refrigerate (2 to 8°C).
Use aseptic technique	No equivalent statement
HOSPIRA logo	No logo
Distr. by Hospira Inc.	Pfizer Canada Inc.
US address	CA Address
Lot and expiry placed vertically	Lot and expiry placed vertically