Important Safety Information
Importation of US-Labelled Rocuronium Bromide Injection Due to Shortage of Canadian-labelled Rocuronium

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 shortage of Rocuronium Bromide Injection, a non-depolarizing neuromuscular blocker (NMB), in Canada as a result of the COVID-19 pandemic.**
- **Given the medical necessity of this product, Health Canada has added US-labelled Rocuronium Bromide Injection 100 mg/10 mL (10 mg/mL) vials in a 10 mL volume to the List of Drugs for Exceptional Importation and Sale.**
- **Pfizer Canada markets the same concentration in Canada (10 mg/mL) but in a 5 mL volume. The product imported from the United States contains double the volume of the Canadian Pfizer product.**
- **Healthcare professionals should be aware that:**
  - **US-labelled Rocuronium Bromide Injection, USP does not have a red ferrule (metal seal on vial) (see Appendix A).**
  - **There is a potential risk of errors resulting from inadvertent selection and administration of NMBs, resulting in serious harm to patients.**
- **Proper selection of intended product must be confirmed to avoid confusion with other injectable solutions.**

What is the issue?
There is an unprecedented demand and shortage of Rocuronium Bromide Injection in Canada as a result of the COVID-19 pandemic. **Given the medical necessity of this product, Health Canada has added US-labelled Rocuronium Bromide Injection 100 mg/10 mL (10 mg/mL) vials in a 10 mL volume to the List of**

Drugs for Exceptional Importation and Sale in accordance with the Interim Order https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/announcements/interim-order-importation-sale-medical-devices-covid-19.html

Products affected
Rocuronium Bromide Injection (US-labelled)
100 mg/10 mL (10 mg/mL); 10 mL volume

Background information
Rocuronium Bromide, a non-depolarizing neuromuscular blocker, is indicated as an adjunct to general anesthesia to facilitate routine endotracheal intubation or rapid sequence (initiated at 60-90 seconds post-administration) intubation to provide skeletal muscle relaxation during surgery or mechanical ventilation.

For information on appropriate use of the imported US-labelled rocuronium bromide including dosage and administration, please refer to the Rocuronium Bromide US Prescribing Information which can be found at http://labeling.pfizer.com/ShowLabeling.aspx?id=4592.

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

In Canada, neuromuscular blockers are commonly supplied with a distinctive red ferrule (metal seal on vial) with white lettering: "Warning: Paralyzing Agent" or "Paralyzing Agent". Canadian healthcare professionals who administer NMBs are accustomed to this labelling and packaging practice, which has been adopted by industry as a strategy to readily identify NMBs so that they are not confused with other products.

Foreign NMB products may have ferrules that aren't red. This is the case for US labelled Rocuronium Injection, USP (see **Appendix A**). This non-standard labelling and packaging may increase the risk of errors in which NMBs are inadvertently selected and administered to patients.

The rocuronium product being made available from the US has a concentration of (10 mg/mL) and a volume of 10 mL. **Pfizer markets the same concentration (10 mg/mL) in Canada but in a 5 mL volume.** Therefore, the product imported from the United States contains **double the volume (10 mL)** of the Canadian product.

The difference in volume of the foreign rocuronium product may increase the risk of the wrong dose being administered and lead to overdoses. Different vial sizes can also cause confusion and result in selection errors.

Health Canada is aware of domestic and international reports of NMB mix-ups causing serious harm including death; some of these errors are related to differences in the labelling and packaging of these products.

Proper selection of intended product must be confirmed to avoid confusion with other injectable solutions.

Action taken by Health Canada
The Minister of Health signed the *Interim Order Respecting Drugs, Medical Devices 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 *List of Drugs for Exceptional Importation and Sale* referenced in the Interim Order are eligible for the exceptional importation and sale provisions provided for in the Interim Order. Health Canada has added Rocuronium Bromide Injection, USP to this list, which permits the importation and sale of US-labelled Rocuronium Bromide injection.

Health Canada has worked with Pfizer Canada ULC to prepare this alert for Rocuronium Bromide. Health Canada is communicating this important safety information to healthcare professionals and Canadians via the Recalls and Safety Alerts Database on the Healthy Canadians Web Site (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 Rocuronium Bromide Injection 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.

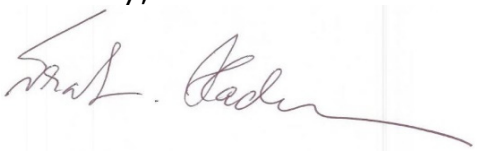
You can report any suspected adverse reactions associated with the use of health products to Health Canada by:

- Calling toll-free at 1-866-234-2345; or
- Visiting MedEffect™ Canada's Web page on Adverse Reaction Reporting (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

Sincerely,



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

Appendix A – Comparison of US-Labelled and Canadian-Labelled Rocuronium Bromide Injection

US CAP	
	 **PARALYZING AGENT IN BLACK INK**

COMPARISON OF VIAL LABELS	
US vial label	**Canadian vial label**
	
English only	English and French
10 mL Rocuronium Bromide Inj. **100 mg/10 mL (10 mg/mL)**	**5 mL** PrRocuronium Bromide Injection **50 mg/5 mL (10 mg/mL)**
For I.V. use only	For I.V. Use Only
WARNING: Paralyzing Agent. Causes Respiratory Arrest. Facilities must be immediately available for artificial respiration.	**PARALYZING AGENT**
NDC 0409-9558-31 Commodity code RL-7146 No Product List Nº	DIN 002318121 Commodity code RL-6953 Product List Nº 09559
Multiple dose vial	Multidose
Stored under Refrigeration at 2° to 8°C (36 to 46°F) DO NOT FREEZE	**Storage:** 2 to 8°C. **Protect from freezing.**
Hospira logo Distr. by Hospira Inc. US address	Pfizer logo Pfizer Canada Inc. CA address