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

STERIMAX
Date: 2020/05/15

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 in Canada of Rocuronium Bromide Injection as a result of the COVID-19 pandemic.**
- **Rocuronium Bromide injection is a non-depolarizing neuromuscular blocking (NMB) agent. Given the medical necessity of this product in Canada, Health Canada has added Sterimax's US-labelled Rocuronium Bromide Injection 50 mg/5 mL (10 mg/mL) vials to the List of Drugs for Exceptional Importation and Sale.**
- **Sterimax's US-labelled Rocuronium Bromide Injection has the same concentration and volume as Rocuronium products authorized in Canada.**
- **Healthcare professionals are advised that:**
  - **US-labelled Rocuronium Bromide Injection does not have a red ferrule (metal seal on vial). Instead, this product has a yellow ferrule (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 the 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 Sterimax's US-labelled Rocuronium Bromide Injection 50 mg/5 mL (10 mg/mL) vials to the List of Drugs for Exceptional Importation and Sale (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).

Products affected
Rocuronium Bromide Injection (US-labelled)
50mg/5 mL (10mg/mL); 5 mL volume

NDC# 70860-651-05
United States Distributor: Athenex, Schaumburg, IL 60173 (USA)
Supplier in Canada for Tier-3 Drug shortages: SteriMax Inc., 2770 Portland Drive, Oakville, ON, L6H 6R4.

Background information
Rocuronium bromide injection is a non-depolarizing neuromuscular blocking agent indicated as an adjunct to general anesthesia to facilitate both rapid sequence and routine tracheal intubation, and 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:
https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=908ce4a4-5628-48dc-b52f-a166358051a9

The US-labelled product comes with a yellow ferrule (metal seal on vial) with black lettering: "Paralyzing Agent" on the immediate container label and is associated with various risk factors including death due to medication error.

Sterimax Inc. currently does not market Rocuronium Bromide Injection in Canada.

Information for healthcare professionals
This drug should be administered by 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 are not red. This is the case for the US-labelled Rocuronium Injection being imported by Sterimax (**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.

Healthcare professionals should be aware that:

- **US-labelled Rocuronium Bromide Injection does not have a red**

ferrule (metal seal on vial). Instead, this product has a yellow ferrule (see Appendix A.)

- **There is a potential risk of errors resulting from inadvertent selection and administration of NMBs, resulting in serious harm to patients.**

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 the 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/drug-products/announcements/interim-order-importation-sale-medical-devices-covid-19.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 is communicating this important safety information to healthcare professionals and Canadians via the Recalls and Safety Alerts Database (https://healthycanadians.gc.ca/recall-alert-rappel-avis/index-eng.php) on the Healthy Canadians Web Site. This communication will be further distributed through the MedEffect™ e-Notice email notification system as well as 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 Sterimax Inc. or Health Canada.

SteriMax Inc.,
2770, Portland Drive, Oakville, ON, L6H 6R4
Phone: +1-800-881-3550
Fax: +1 -877-546-7667
E-mail: pv@sterimaxinc.com

To correct your mailing address or fax number, contact Sterimax Inc.

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 (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html) 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:

Regulatory Operations and Enforcement Branch
E-mail: hc.hpce-cpsal.sc@canada.ca

Original signed by

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Appendix A – Images for Sterimax's US-labelled Rocuronium Bromide Injection

1. **Product vial**

2. **Product Label**

3. **Product Cap**