

Important Safety Information
Importation of US-Labelled Rocuronium Bromide Injection distributed by
Avir Pharma Inc. Due to Shortage of Canadian-labelled Rocuronium



2020/05/25

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 increased demand and shortage of Rocuronium Bromide Injection in Canada 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 US-labelled Rocuronium Bromide Solution for Injection 50 mg/5 mL (10 mg/mL) to the List of Drugs for Exceptional Importation and Sale.**
- **Avir Pharma Inc. will distribute US-labelled Rocuronium Bromide Injection, which has the same concentration and volume as rocuronium products authorized in Canada.**
- **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 with the warning "PARALYZING AGENT" in black lettering (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 increased demand for 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 50 mg/5 mL (10 mg/mL) vials in a 5 mL volume 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). <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**)
50 mg/5 mL (10mg/mL); 5 mL volume

NDC #70860-651-05; 70860-651-41

Canadian Importer: Laboratoire Riva Inc.

Canadian Distributor: Avir Pharma Inc.

United States Distributor and Labeller: Athenex Pharmaceutical Division, LLC

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](https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=908ce4a4-5628-48dc-b52f-a166358051a9&type=display).
<https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=908ce4a4-5628-48dc-b52f-a166358051a9&type=display>

The US-labelled product comes with a yellow ferrule (metal seal on vial) with the warning "Paralyzing Agent" in black lettering in place of a red ferrule.

Information for healthcare professionals

Rocuronium Bromide 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 are not red. This is the case for the US labelled Rocuronium Injection being distributed by Avir Pharma Inc. (see Appendix A). This non-standard labelling and packaging may increase the risk of errors where 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 with the warning “Paralyzing Agent” in black lettering (see Appendix A.)**
- **There is a potential risk of errors resulting from inadvertent selection and administration of NMBs, resulting in serious harm to patients.**

Institutions should confirm that barcode systems provide correct information when the product is scanned. The barcode used on US-labelled Rocuronium Bromide Injection may not be recognized by scanning systems used in Canada.

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](#). 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 to this list, which permits the importation and sale of US-labelled Rocuronium Bromide injection.

Health Canada has worked with Avir Pharma Inc. 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 healthcare professionals and consumers reporting them. Any case of serious or unexpected side effects in patients receiving US-labelled Rocuronium Bromide Injection should be reported to Avir Pharma Inc. or Health Canada.

Avir Pharma Inc.
660 Boul. Industriel
Blainville, QC, Canada
J7C 3V4
1-800-363-7988

To correct your mailing address or fax number, contact Avir Pharma.

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) (<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

Sincerely,



Olivier St-Denis
President, Avir Pharma Inc.

Appendix A - Images of the US-Labelled Rocuronium Bromide Injection distributed by Avir Pharma Inc.

