Institute for Safe Medication Practices Canada
REPORT MEDICATION INCIDENTS
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A KEY PARTNER IN
CMIRPS Canadian Medication Incident Reporting and Prevention System
SCDPIM Système canadien de déclaration et de prévention des incidents médicamenteux

ISMP Canada Safety Bulletin

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ALERT: Rocuronium Vials Lack Recommended Warning on Ferrule

- Rocuronium 50 mg/5 mL (from Auro Pharma Inc.) has the warning "**Paralyzing Agent**" on the cap but lacks this warning on the ferrule (Figure 1); this is inconsistent with safety recommendations designed to mitigate the risk of errors with neuromuscular blocking agents.
- The warning on the vial label is hidden behind a peel away label (Figure 1) instead of being prominently displayed on the principal display panel.
- Risk reduction strategies are needed—in particular, applying end-user warnings to the vial and alerting staff—until planned changes are made by the manufacturer and the existing supply is depleted.

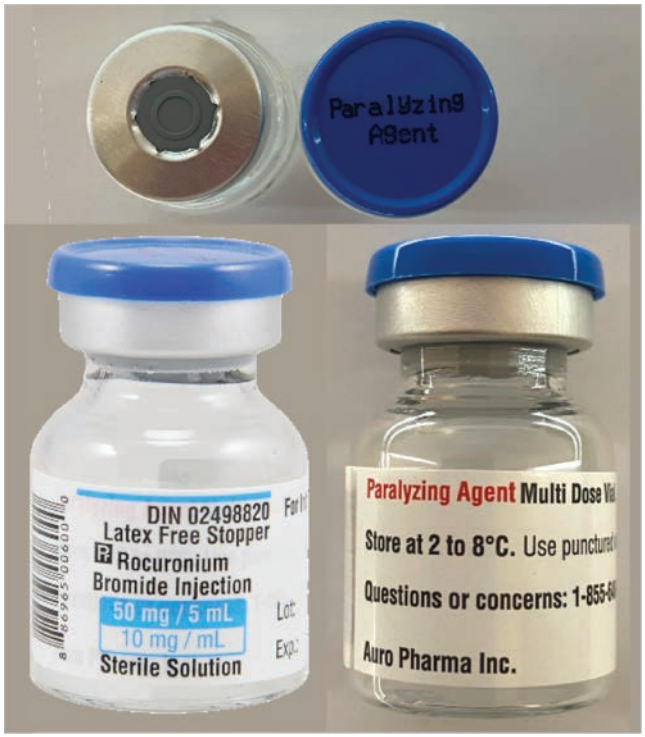

Figure 1. Auro rocuronium vials without the "Paralyzing Agent" warning on the ferrule, nor prominently displayed on the principal display panel. (Image courtesy of Auro Pharma Inc.)

BACKGROUND

The current COVID-19 pandemic has increased the demand for certain critical medications. The neuromuscular blocking agent rocuronium is one such medication. Neuromuscular blocking agents are high-alert medications and, when used in error, can lead to devastating injuries or death.[1]

SAFETY CONCERN

In accordance with recommendations established to address selection errors at the point of care,[2,3] neuromuscular blocking agents in Canada should carry a prominent warning on the vial labels, cap, and ferrule.[3] The Auro product does not carry the recommended warning on its ferrule, nor does it prominently display the warning on the principal display panel. It also lacks the recommended red cap and red ferrule with the warning in white lettering. This deviation from safe labelling and packaging recommendations increases the risk that this product may be misidentified and inadvertently administered.[4]

RESPONSIVE ACTION

HealthPRO Procurement Services Inc. has communicated with Auro about the risk. The company has indicated that they will be changing the cap and ferrule to red, both of which will display the warning "Paralyzing Agent" in white letters (Figure 2). Auro will redesign the vial label to prominently display the warning on the principal display panel (Figure 2). The company will also provide an auxiliary label that includes the warning, for application to syringes. Auro has submitted the label changes to Health Canada for approval; however, until the new format becomes available, hospitals may be accessing the original supply. Auro and other Canadian manufacturers are to be commended for voluntarily implementing safety recommendations for labelling and packaging of neuromuscular blocking agents.[2]

Figure 2. Proposed improvements for Auro rocuronium vials: the "Paralyzing Agent" warning in white lettering on the red cap and red ferrule, and prominently displayed on the principal display panel (Images courtesy of Auro Pharma Inc.)

RISK MITIGATION STRATEGIES

In the interim, until the current supply is exhausted AND the new stock is in use, hospitals that purchase the Auro rocuronium product should take the following precautions:[1,4]

- Apply end-user warnings, such as an auxiliary label indicating "Paralyzing Agent", on the vial.
- Review how and where the product is stored, to ensure that such warnings are clearly visible.
- Assess the risk of a look-alike mix-up with existing products in the pharmacy, intensive care unit, or other areas where rocuronium would be used.
- Where available, use bar-code scanning technology throughout the medication-use process.
- Alert staff about the risk of errors.

ACKNOWLEDGEMENTS

ISMP Canada gratefully acknowledges HealthPRO Procurement Services Inc. for identifying the risk and for their contributions to this alert.

REFERENCES

1. Special alert! Prepare for vials of neuromuscular blocking agents without cap warnings. Horsham (PA): Institute for Safe Medication Practices; 2020 Jun 4 [cited 2020 Apr 22]. Available from: https://ismp.org/resources/special-alert-prepare-vials-neuromuscular-blocking-agents-without-cap-warnings
2. Neuromuscular blocking agents: sustaining packaging improvements over time. ISMP Can Saf Bull. 2014 [cited 2021 Apr 21];14(7):1-5. Available from: https://www.ismp-canada.org/download/safetyBulletins/2014/ISMPCSB2014-7_NeuromuscularBlockingAgents.pdf
3. Good label and package practices guide for prescription drugs. Toronto (ON): Institute for Safe Medication Practices Canada; 2019 Jun [cited 2021 Apr 21]. Available from: https://www.canada.ca/en/health-canada/services/drugs-health-products/reports-publications/medeffect-canada/good-label-package-practices-guide-prescription-drugs-profile/guidance-document.html
4. Neuromuscular blocking agents—time for action. ISMP Can Saf Bull. 2002 [cited 2021 Apr 22];2(12):1-3. Available from: https://www.ismp-canada.org/download/safetyBulletins/ismpcsb0212.pdf

Hospital Readiness to Use the Antidote Methylene Blue

ISMP Canada became aware of incidents that described an immediate need for methylene blue as an antidote to treat methemoglobinemia (resulting from sodium nitrate/nitrite exposure). In these urgent situations, there was confusion as to its availability and dosing, resulting in delays in administration.

Information about methylene blue dosing and administration, adverse effects, and monitoring parameters can be found on the *Canadian Antidote Guide in Acute Care Toxicology* website:[1]
https://www.ciusss-capitalenationale.gouv.qc.ca/en/antidotes/methylene-blue

Recommendations for Hospitals

- Verify that an adequate supply of methylene blue is available *in the emergency department*. A minimum of 10 x 50 mg vials may be needed in a 24-hour period to treat a 70 kg person.[1]
- Ensure that staff are familiar with the location of the antidote stock and have readily available information to support its use.
- Contact the provincial/territorial poison centre for additional patient care guidance, if considering the use of methylene blue.

Acknowledgements

ISMP Canada thanks the Toxicovigilance Canada Network and Margaret Thompson MD FRCPC, Medical Director, Ontario, Manitoba & Nunavut Poison Centres, Toronto, ON.

Reference

1. Methylene blue [monograph]. Centre intégré universitaire de santé et de services sociaux de la Capitale-Nationale. Canadian Antidote Guide in Acute Care Toxicology. 2020 Jul 10 [cited 2021 Jan 19]. Cited https://www.ciusss-capitalenationale.gouv.qc.ca/en/antidotes/methylene-blue

SafeMedicationUse.ca

Newsletter:

Safer Choices for Pain Control after Wisdom Tooth Removal

SafeMedicationUse.ca received a report about a teenage patient who was given a prescription for an opioid to treat acute pain after wisdom tooth removal. The teen's parent was familiar with the risks associated with opioid use and looked for safer options. Instead of the opioid originally prescribed, the pain was managed with naproxen, a non-steroidal anti-inflammatory pain medication.

Tips for Practitioners

- Suggest that patients start with a non-opioid pain reliever such as acetaminophen, ibuprofen, or naproxen, *before* trying opioids for the acute pain.
- If opioid pain relievers are needed, limit the quantity prescribed or dispensed to 3 days or less. Inform the patient that less medication will be needed as the pain symptoms resolve.

Read the full newsletter here: https://safemedicationuse.ca/newsletter/wisdom-tooth-pain.html

CMIRPS SCDPIM
Canadian Medication Incident Reporting and Prevention System
Système canadien de déclaration et de prévention des incidents médicamenteux

The Canadian Medication Incident Reporting and Prevention System (CMIRPS) is a collaborative pan-Canadian program of Health Canada, the Canadian Institute for Health Information (CIHI), the Institute for Safe Medication Practices Canada (ISMP Canada) and the Canadian Patient Safety Institute (CPSI). The goal of CMIRPS is to reduce and prevent harmful medication incidents in Canada.

HIROC

The Healthcare Insurance Reciprocal of Canada (HIROC) provides support for the bulletin and is a member owned expert provider of professional and general liability coverage and risk management support.

ISMP CANADA

The Institute for Safe Medication Practices Canada (ISMP Canada) is an independent national not-for-profit organization committed to the advancement of medication safety in all healthcare settings. ISMP Canada's mandate includes analyzing medication incidents, making recommendations for the prevention of harmful medication incidents, and facilitating quality improvement initiatives.

Report Medication Incidents

(Including near misses)

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ISMP Canada strives to ensure confidentiality and security of information received, and respects the wishes of the reporter as to the level of detail to be included in publications. Medication Safety bulletins contribute to Global Patient Safety Alerts.

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