

International Medication Safety Network

Neuromuscular Blocking Agents Safety Interest Group

Update from Health Canada
January 18, 2024



Outline

- Importation of foreign-labelled neuromuscular blocking agents as a result of the COVID-19 pandemic
- Case study on the labelling and packaging of a neuromuscular blocking agent

IMPORTATION OF FOREIGN- LABELLED NMBs

Example of an Imported Product with Foreign Labelling

US VIAL



**PARALYZING
AGENT IN
BLACK INK**



10 mL Multiple-dose Rx only
**Pancuronium Bromide
Injection, USP**

10 mg/10 mL (1 mg/mL)

WARNING: Paralyzing Agent
FOR INTRAVENOUS USE.

LOT ##-###-AA

EXP DMMYYYY

NDC 0409-4646-11

WARNING: Paralyzing Agent. Causes Respiratory Arrest.
Facilities must be immediately available for artificial respiration.
Each mL contains pancuronium bromide 1 mg; sodium acetate, anhydrous 1.2 mg; benzyl alcohol 10 mg (as preservative). NaCl added to adjust tonicity. May contain acetic acid and/or NaOH for pH adjustment. pH 4.0 (3.8 to 4.2). **Usual dosage:** See insert. **Refrigerate at 2° to 8°C (36° to 46°F).**

Dist. by Hospira, Inc., Lake Forest, IL 60045 USA R L - 7 2 1 5

FPO / 7.5 Mil

English only

Pancuronium Bromide Injection, USP, 10 mg/10 mL (1 mg/mL)

Rx only

Foreign Labelling continued

- Non-standard ferrule colour with white lettering: "WARNING: PARALYZING AGENT" OR "PARALYZING AGENT".
- Reports of NMB mix-ups causing serious harm including death; some of these errors related to differences in the labelling and packaging.
- Proper selection of intended product must be confirmed to avoid confusion with other injectable solutions.

Communication on Foreign-Labelled Products

- Risk communications prepared collaboratively
- Recalls and Safety Alerts Database on the Healthy Canadians website
- MedEffect e-Notice email notification system
- Social media: LinkedIn and Twitter



The screenshot shows the Government of Canada website interface. At the top left is the Canadian flag and the text "Government of Canada" and "Gouvernement du Canada". To the right is a search bar with the text "Search website" and a magnifying glass icon. Below the header is a breadcrumb trail: "Canada.ca > Health > Recalls and safety alerts". A dark blue banner contains the text "Recalls and safety alerts". Below this is the text "Health professional risk communication". The main heading is "Importation of US-Labelled Rocuronium Bromide Injection Due to Shortage of Canadian-labelled Rocuronium". Below the heading is a table of details:

Starting date:	May 25, 2020
Posting date:	May 25, 2020
Type of communication:	Dear Healthcare Professional Letter
Subcategory:	Drugs
Source of recall:	Health Canada
Issue:	Important Safety Information, Supply, Product Safety
Audience:	Healthcare Professionals, Hospitals
Identification number:	RA-73169

Last updated: 2020-05-25

CASE STUDY

Labelling and Packaging of Cisatracurium

- Canadian manufacturer proposed the use of an alternative colour for the aluminum seal of their cisatracurium product.
- Temporary use of a red seal due to reduced supply of aqua aluminum seal.
- Revert to the original aqua coloured aluminum seal once more inventory received.
- Health Canada requested that the manufacturer consider the change be a permanent change in Canada.

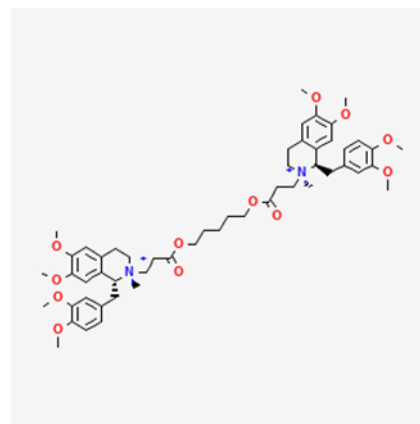
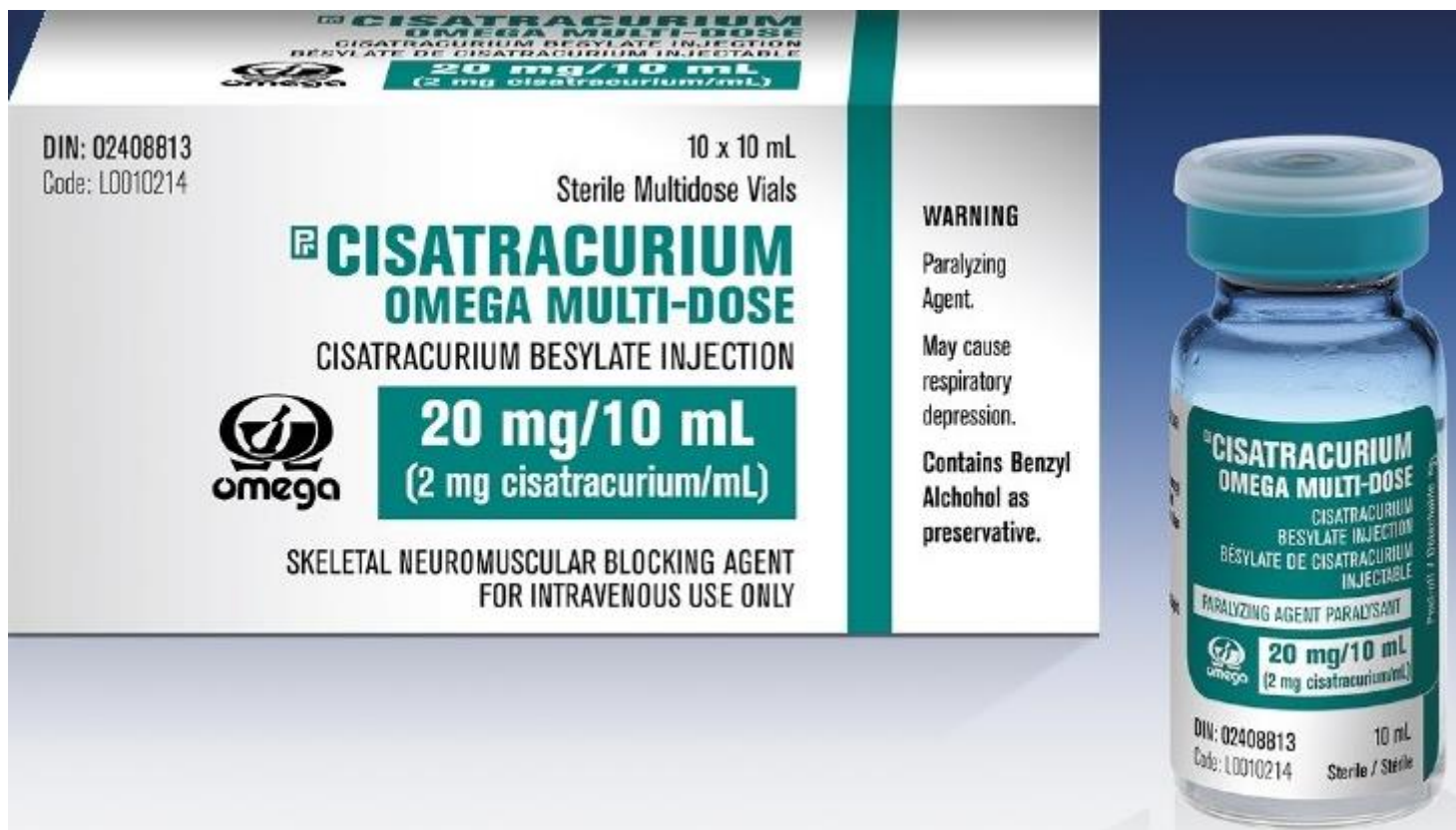


Image of the Canadian Cisatracurium Product



Canadian Neuromuscular Blocking Agents



Case Study continued

- Manufacturer: well-established product
- Warning on the vial closure consistent with USP standard
- Joint communication of temporary colour change to maintain supply in Canada
- Change would require support to end-users (i.e., educational materials)

Cisatracurium Omega Multi-Dose (Cisatracurium Besylate Injection): Temporary change of ferrule (metal seal) colour to maintain continued supply in Canada

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Questions?

