

# Neuromuscular Blockers: Safety Measures and Labeling Requirements

IMSN Neuromuscular Blocker Safety Interest Group

الهيئة العامة للغذاء والدواء  
Saudi Food & Drug Authority



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# Outline

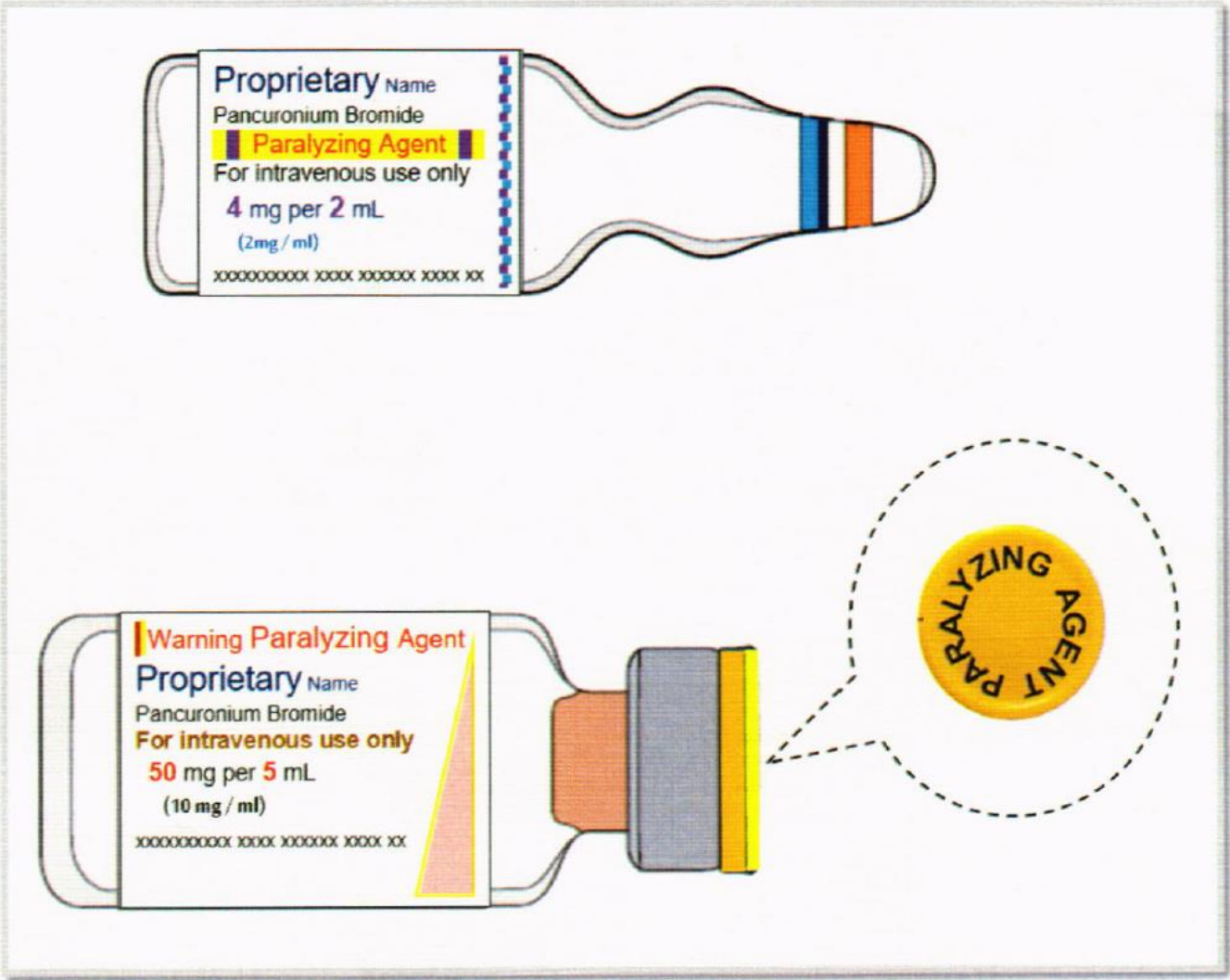
- Registered Neuromuscular Blocking Agents (NMBs) List
- Packaging Type
- Warning Statement
- Med Error Reports

# Registered NMBs List

Scientific Name	Trade Name	Package Type	Marketing Company	Marketing Country	Manufacture Name	Manufacture Country
Atracurium Besilate	Atacure 50 mg/ 5mL and 25 mg/2.5 mL (10 mg/mL) Solution for Injection/Infusion	Ampoule	Hikma Pharmaceuticals PLC	Jordan	Hikma Pharmaceuticals PLC	Jordan
Atracurium Besilate	Atracurium Besylate 50 mg/ 5mL and 25 mg/2.5 mL (10 mg/mL) Solution for Injection	Ampoule	HOSPIRA UK LIMITED	United Kingdom	Wasserburger Arzneimittelwerk GmbH	Germany
Cisatracurium	Nimbex 20 mg/10 mL and 5 mg/ 2.5 mL (2 mg/mL) Solution for Injection	Ampoule	Aspen Pharma Trading Limited	Ireland	GlaxoSmithKline (GSK)	Italy
Cisatracurium	Nimbex 150 mg/30 mL (5 mg/mL) Solution for Injection	Vial	Aspen Pharma Trading Limited	Ireland	GlaxoSmithKline (GSK)	Italy
Cisatracurium	Sisacure 20 mg/ 10 mL (2 mg/mL) Solution for Injection/Infusion	Ampoule	Jazeera Pharmaceutical Industries (JPI)	Saudi Arabia	Hikma Italia Spa	Italy
Cisatracurium	CIS-TAC 10 mg/5 mL (2 mg/mL) Solution for Injection/Infusion	Ampoule	Fresenius Kabi Deutschland GmbH	Germany	Fresenius Kabi Manufacturing Sa (Pty) Ltd	South Africa
Cisatracurium	Traxia 20 mg/10 mL and 10 mg/ 5 mL (2 mg/mL) Solution for Injection	Vial	MS Pharma Saudi (MSPS)	Saudi Arabia	Ms Pharma	Jordan
Cisatracurium	Bexenta 10 mg/ 5 mL (2 mg/mL) Solution for Injection	Ampoule	SPIMACO ADDWAEIH	Saudi Arabia	SPIMACO Addwaeih	Saudi Arabia
Cisatracurium	Salocan 20 mg/10 mL and 10 mg/ 5 mL (2 mg/mL) Solution for Injection	Ampoule	Tabuk Pharmaceutical Manufacturing Company	Saudi Arabia	Tabuk Pharmaceutical Manufacturing Co.	Saudi Arabia
Pancuronium Bromide	Alpax 4 mg/2 mL (2 mg/mL) Solution for Injection	Ampoule	Hikma Pharmaceuticals PLC	Jordan	Hikma Farmaceutica	Portugal
Rocuronium Bromide	Esmeron 50 mg/ 5 mL (10 mg/mL) Solution for Injection	Vial	Merck Sharp & Dohme B.V	Netherlands	N.V. Organon	Netherlands
Rocuronium Bromide	Rucoron 50 mg/ 5mL (10 mg/mL) Solution for Injection/Infusion	Vial	Jazeera Pharmaceutical Industries (JPI)	Saudi Arabia	Hikma Farmaceutica	Portugal
Rocuronium Bromide	Rocuronium Bromide BOS 50 mg/ 5mL (10 mg/mL) Solution for Injection	Vial	Boston Oncology Arabia	Saudi Arabia	Gland Pharma Limited	India
Suxamethonium Chloride	Suxamethonium Chloride Martindale 100 mg/ 2 mL (50 mg/mL) Solution for Injection	Ampoule	MARTINDALE PHARMACEUTICALS LTD TRADING AS MARTINDALE PHARMA	United Kingdom	Macarthy's Laboratories Limited T\A Martindale Pharma	United Kingdom

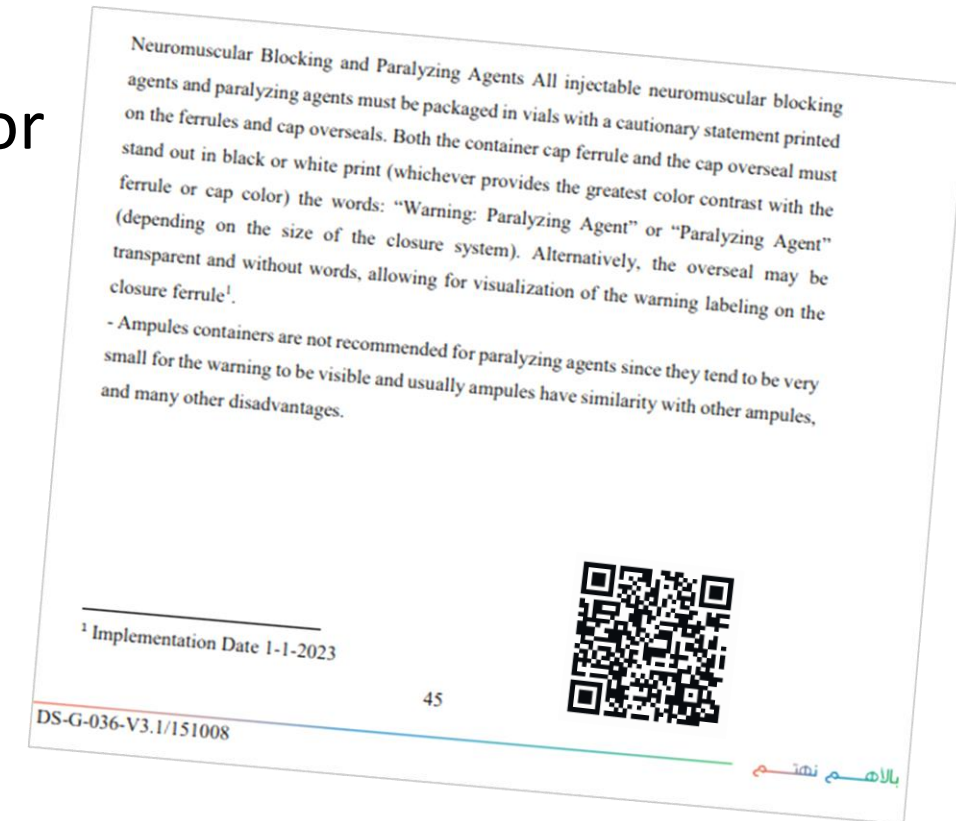


# Circular



# Labeling Requirements

- The warning statement is a requirement for new submissions since November 2022.
- Implementation Date 1-1-2023.



# Package Type

- Among registered products, 13 out of 19 (~ 70%) are packaged in Ampules



# Ampule Limitations

- Small containers
- Small print labels
- Labels on clear glass and difficult to read
- Look alike in size and shape
- Barcode printing and scanning
- Warning statements
- Glass ampules and filter needle use



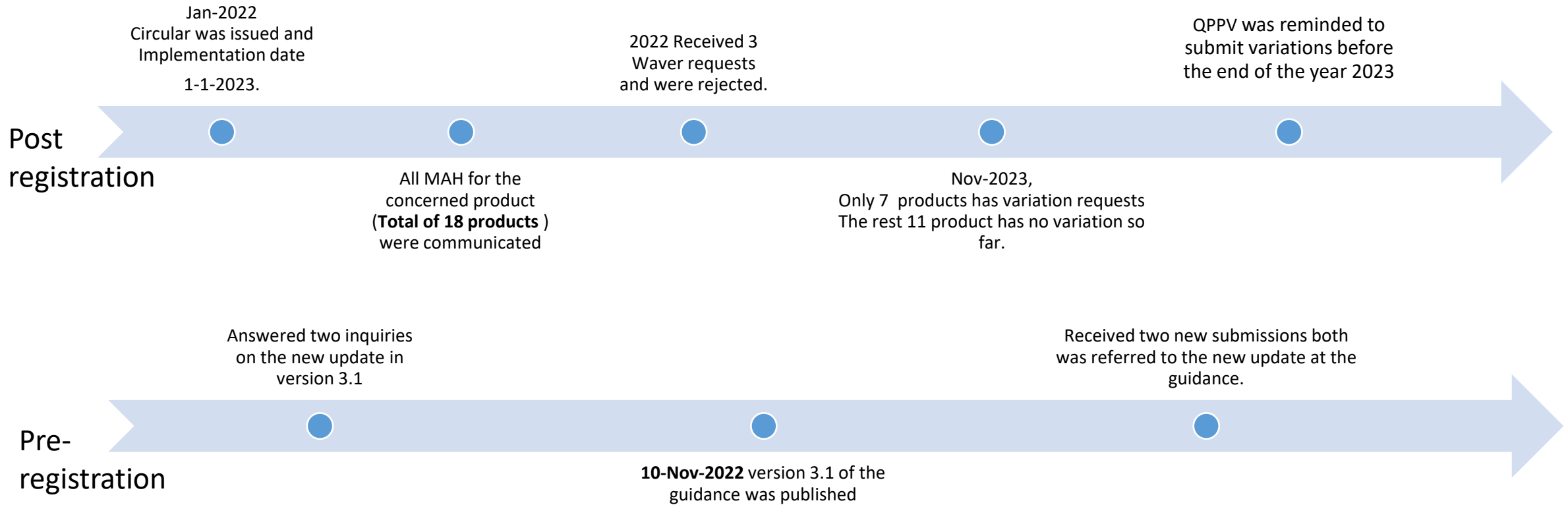
ISMP Canada. ISMP Canada Safety Bulletin. 2004;4(11):1-2.  
ISMP. ISMP Medication Safety Alert! Acute Care. 2023;28(17):1-4.  
ISMP. ISMP Safe Practice Guidelines for Adult IV Push Medications. ISMP; 2015



# Effective Communication of Warnings

- “WARNING: CAUSES RESPIRATORY ARREST – PATIENT MUST BE VENTILATED”
- “WARNING: PARALYZING AGENT – CAUSES RESPIRATORY ARREST”
- “WARNING: CAUSES RESPIRATORY PARALYSIS – PATIENT MUST BE VENTILATED”

# Timeline for Change



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Reports?

# Rucoron (Rocuronium Bromide) 50mg/ 5mL (10 mg/mL) Injection — Strength Expression Report



# Rucoron (Rocuronium Bromide) 50mg/ 5mL (10 mg/mL) Injection

**Warning: Paralyzing agent.**  
For Intravenous Use  
Solution for Injection  
Store in a refrigerator (2-8°C).  
Store in the original package in order to protect from light.

MAH: Jazeera Pharmaceutical Industries,  
Riyadh - Saudi Arabia  
Manufacturer: Hikma Farmaceutica (Portugal),  
S.A., Sintra - Portugal  
Rev. 06/2023 2LRUC05000-KSA

**Rucoron®**  
Rocuronium bromide

50 mg per 5 ml (10 mg/ml) (5 ml)

**hikma.**

Unvarnished area

Batch: :  
Mfg. :  
Exp. :

