



Neuromuscular Blocker (NMB) Gaps and Solutions

10/01/2024



LIST OF REGISTERED NMB

Generic Name and Strength	Manufacturer Name	Product Name
Atracurium Besilate : 10 mg/ml Solution For Injection	The Wellcome Foundation Limited, UNITED KINGDOM	TRACRIUM
Atracurium Besilate : 10 mg/ml Solution For Injection	Hameln Pharmaceuticals GmbH, GERMANY	ATRACURIUM-HAMELN
Atracurium Besilate : 10 mg/ml Solution For Injection	Glaxo Wellcome S.p.A., ITALY	TRACRIUM
Atracurium Besilate : 10 mg/ml Solution For Injection	Abbott Laboratories, U.S.A	ATRACURIUM BESYLATE
Cisatracurium Besilate : 2 mg/ml Solution For Injection	A S Kalceks, Latvia	Cisatracurium Kalceks
Cisatracurium Besilate : 2 mg/ml Solution For Injection	Al Hikma Pharmaceuticals, JORDAN	SISACURE
Cisatracurium Besilate : 2 mg/ml Solution For Injection	GlaxoSmithKline S.p.A., ITALY	NIMBEX
Cisatracurium Besilate : 5 mg/ml Solution For Injection	Glaxo Wellcome S.p.A., ITALY	NIMBEX FORTE
Cisatracurium Besilate : 2 mg/ml Solution For Injection	Fresenius Kabi Deutschland GmbH, GERMANY	CISATRACURIUM KABI

LIST OF REGISTERED NMB

Generic Name and Strength	Manufacturer Name	Product Name
Pancuronium Bromide : 2 mg/ml Solution For Injection	N.V. Organon, NETHERLANDS	PAVULON
Pancuronium Bromide : 2 mg/ml Solution For Injection	David Bull Laboratories, AUSTRALIA	PANCURONIUM
Rocuronium Bromide : 10 mg/ml Solution For Injection	Labatec-Pharma S.A., SWITZERLAND	ROCALM
Rocuronium Bromide : 10 mg/ml Solution For Injection	Al Hikma Pharmaceuticals, JORDAN	ROCURON
Rocuronium Bromide : 10 mg/ml Solution For Injection	N.V. Organon, NETHERLANDS	ESMERON
Rocuronium Bromide : 10 mg/ml Solution For Injection	Labatec-Pharma S.A., SWITZERLAND	ROCRON
Vecuronium bromide : 10 mg Powder For Solution For Injection	N.V. Organon, NETHERLANDS	NORCURON
Mivacurium Chloride : 2 mg/ml Solution For Injection	The Wellcome Foundation Limited, UNITED KINGDOM	MIVACRON
Suxamethonium Chloride : 10 mg Solution For Injection	Laboratoire Aguettant, FRANCE	SUXAMETHONIUM AGUETTANT
Suxamethonium Chloride : 50 mg/ml Solution For Injection	The Wellcome Foundation Limited, UNITED KINGDOM	ANECTINE (MIDARINE)



Gaps

Recently NMB approved products include the following:

- **Warning: Paralyzing agent.**
Causes respiratory arrest.
Facilities must be immediately available for artificial respiration.



NMB Registration

- The PILs to be approved are cross checked against reference PILs from recognized regulatory authorities, accordingly any such warnings will reflect in those references.
- The registration reviews the artworks based on the approved artworks in reference country like USFDA,EMA etc.

Neuromuscular Blocker Safety

1. kindly choose the NMB agent that is available in your facility

- Pancuronium
- Rocuronium
- Vecuronium
- Atracurium
- Mivacurium
- Cisatracurium
- Suxamethonium
- Other

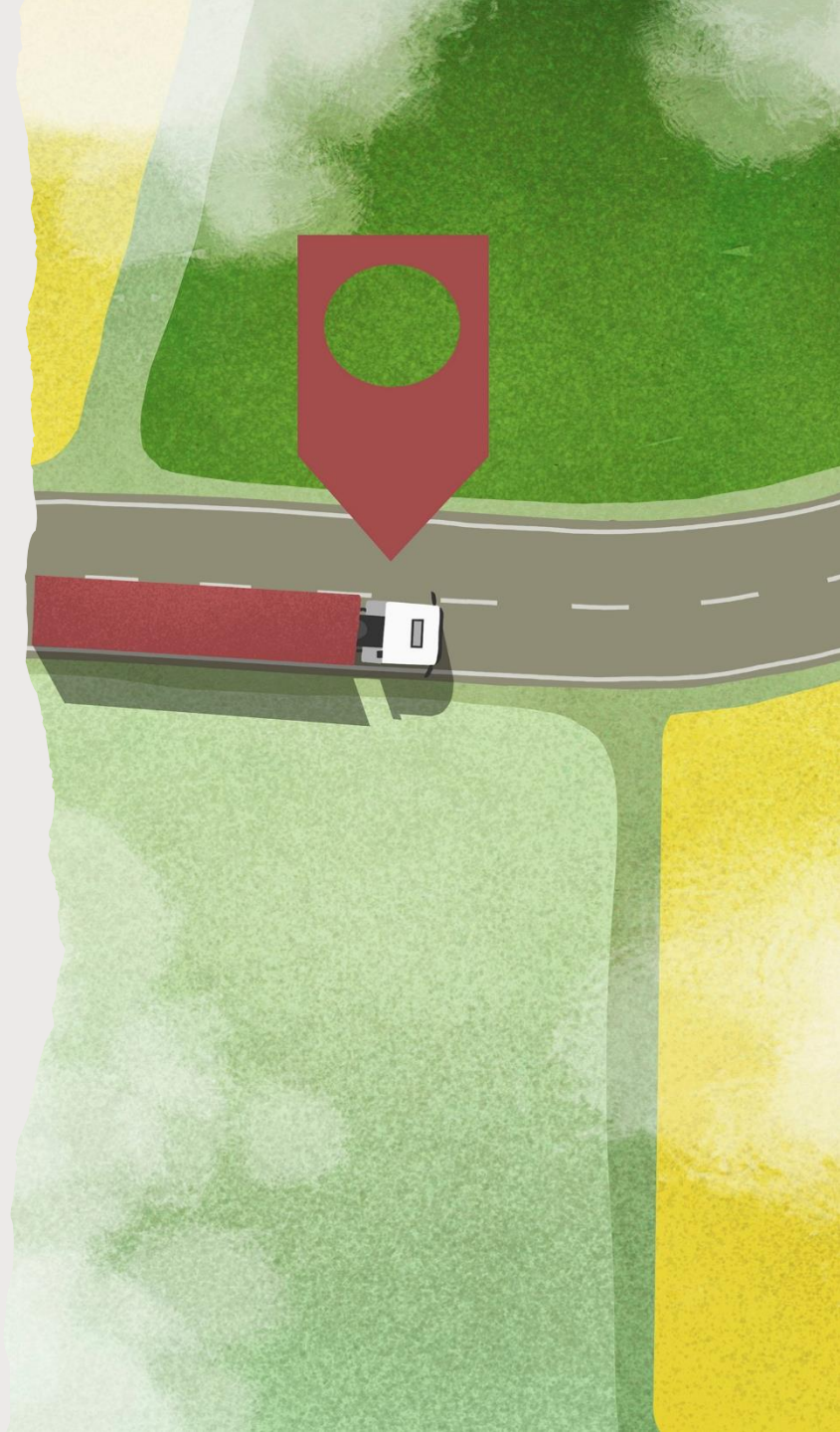
2. Is there any warning on the outer & inner pack of the NMB "Caution Patient Must Be Ventilated, patient shall be in ventilation etc."? *

- Yes
- No

3. Facility name *

Enter your answer

- Short survey has been shared to all PV focal points at hospitals in Emirate of Abu Dhabi, asking for the NMB available and if any warning on the outer and inner pack of NMB “Causes Respiratory Arrest – Patient must be ventilated, patient shall be in ventilation etc.”



2. Is there any warning on the outer & inner pack of the NMB "Causes Respiratory Arrest — Patient Must Be Ventilated, patient shall be in ventilation etc."?

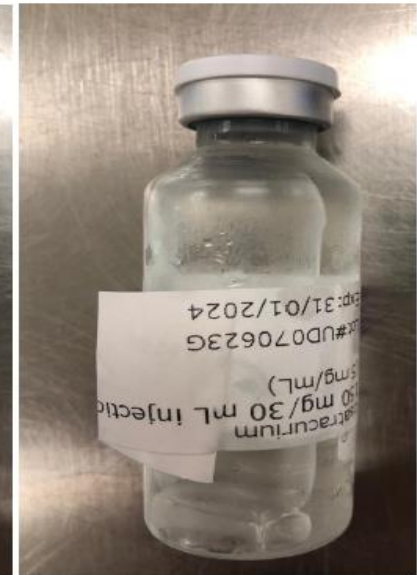
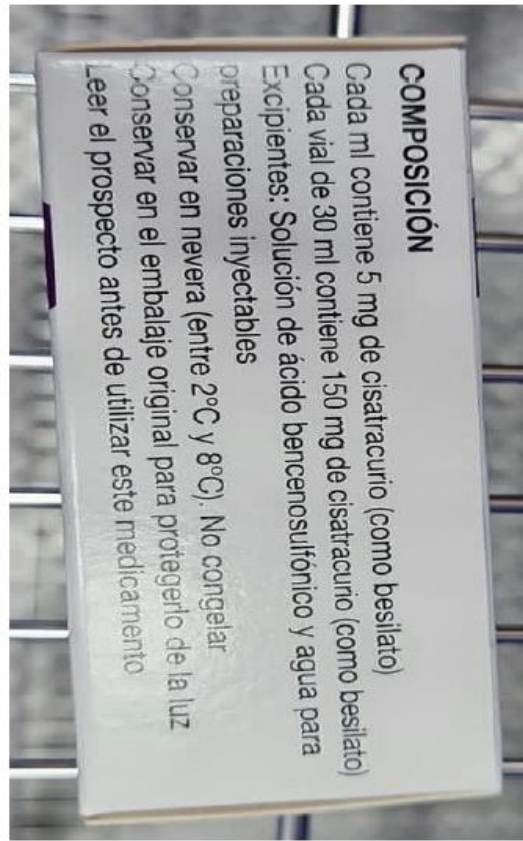
[More Details](#)



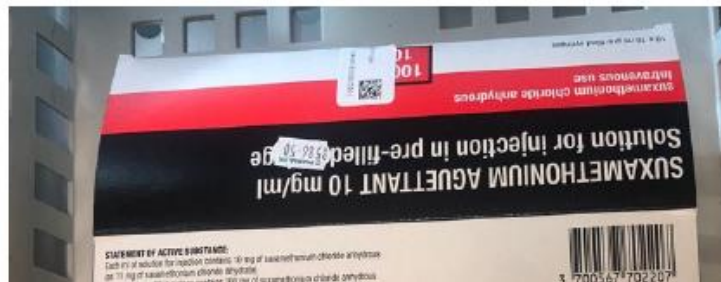
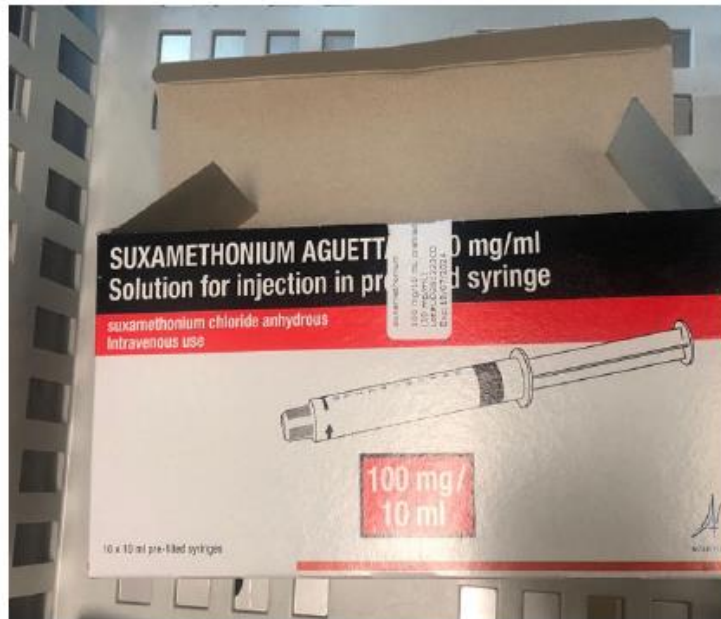
CISATRACURIUM (NORMON®)

CONCERN

- No "Paralyzing Agent" on the cap as recommended by FDA
- No indication anywhere on package that it is a paralyzing agent
- Labeling in Spanish

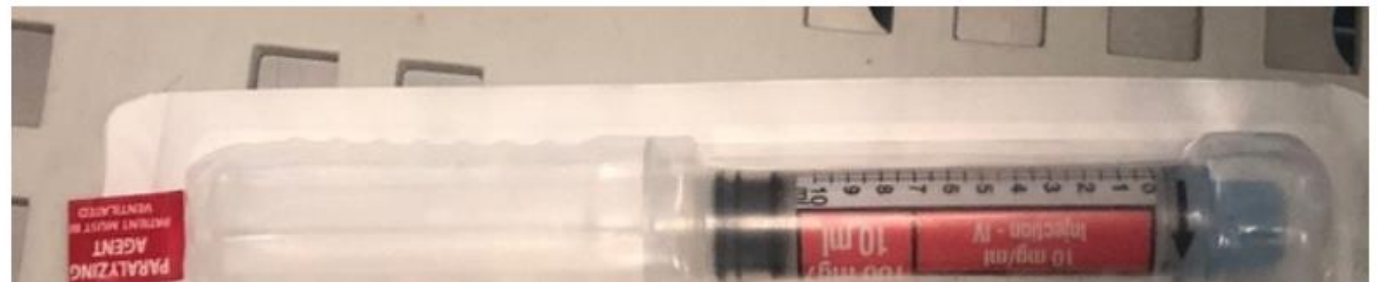


SUXAMETHONIUM PRE-FILLED SYRINGE



CONCERN

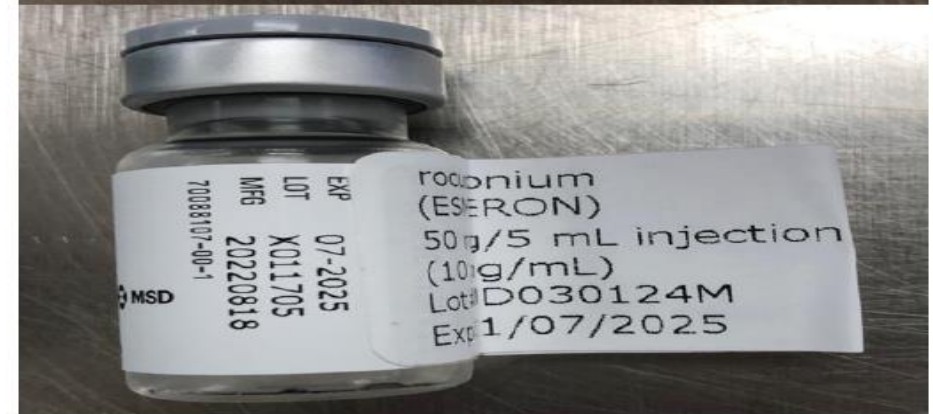
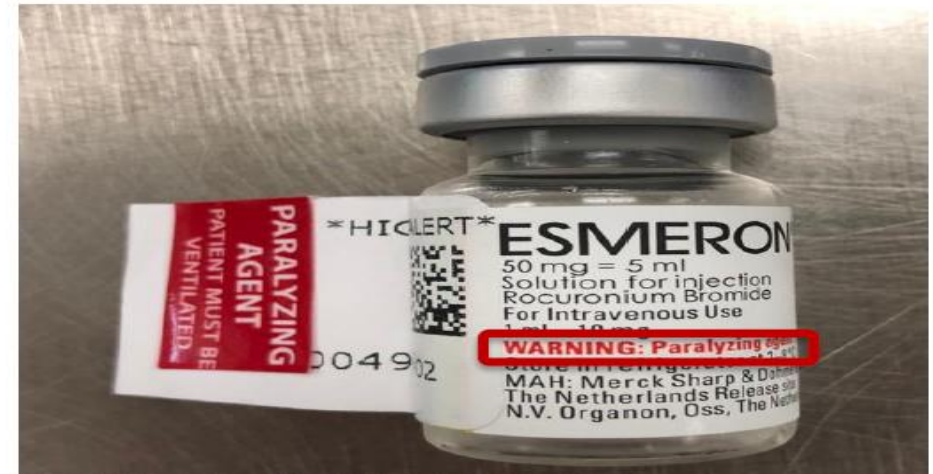
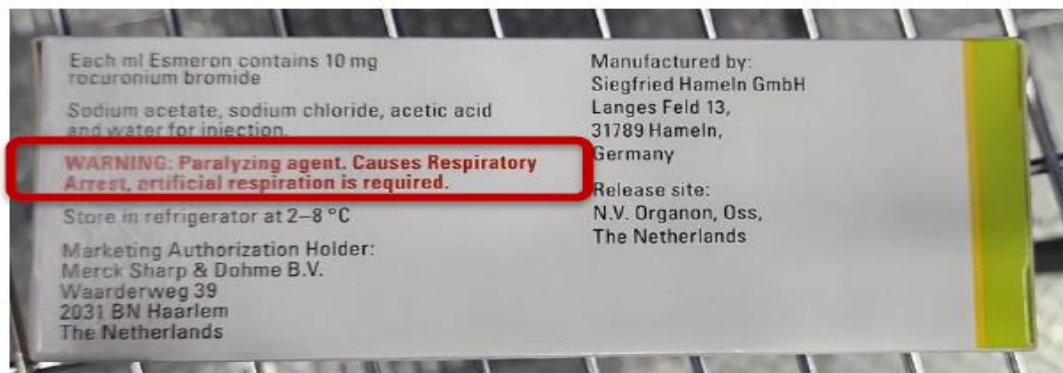
- No indication anywhere on package by the manufacturer that it is a paralyzing agent




ROCURONIUM (ESMERON®)

CONCERN

- No "Paralyzing Agent" on the cap as recommended by FDA





 1 PUSH ON THE PLUNGER TO FREE THE BUNG
 2 TWIST OFF THE END CAP TO BREAK THE SEALS
 Keep the pre-filled syringe in its unopened blister until use.

SUXAMETHONIUM AGUETTANT 10 mg/ml
Solution for injection in pre-filled syringe
100 mg / 10 ml


suxamethonium chloride anhydrous - IV
 Store in a refrigerator (2°C - 8°C). Do not freeze.
 After opening, the medicinal product must be used immediately.

Discard 30 days after first release date.

Batch: E0583A03
 EXP: 03 05 2024
 Mfg.: 04 05 2022 10:40

POTENTIAL TO CAUSE UNINTENDED PARALYSIS, RESPIRATORY ARREST, SEVERE PERMANENT HARM, OR DEATH – PATIENT MUST BE VENTILATED

AGUETTANT



ESMERON®
50 mg = 5 ml
 Rocuronium Bromide


10 vials each vial contains 5ml
 For Intravenous use

POTENTIAL TO CAUSE UNINTENDED PARALYSIS, RESPIRATORY ARREST, SEVERE PERMANENT HARM, OR DEATH – PATIENT MUST BE VENTILATED

0 mg

MSD

POTENTIAL TO CAUSE UNINTENDED PARALYSIS, RESPIRATORY ARREST, SEVERE PERMANENT HARM, OR DEATH – PATIENT MUST BE VENTILATED



NIMBEX™
 intravenous Injection
 Cisatracurium besylate

20 mg cisatracurium (bis-cation) in 10 ml
 5 ampoules

For intravenous injection

10 ml



Recommendation

- Neuromuscular blocking agents registered to include clear visualized warning “paralyzing agents”

DoH pharmacovigilance team reach out all focal points at hospitals in Emirate of Abu Dhabi asking for:

- Reporting medication errors and safety issues regarding the use of neuromuscular blockers (NMB).
- Current practice used and the changes/recommendations done regarding the safe use of neuromuscular blockers (NMB)



Current Practice



Storage
01

02
Prescribing

Dispensing/
Preparation
03

Administration
04

05
Monitoring

Education
06

Storage

- High alert medication
- The storage compartments labelled as “High Alert” AND “Paralyzing agent – causes respiratory arrest” with a printed label specifying drug description.
- Auxiliary labels "Paralyzing agent causes respiratory arrest".
- Pharmacy keeps a mobile intubation kit “containing NMBAs” which is delivered when intubation is performed outside critical areas.



Prescribing

- Appears in red font at time of prescribing, and flagged as “High Alert”.
- Prescribing NMBAs triggers a patient-specific & real-time clinical decision support alerts.





Dispensing/ Preparation

- Each syringe prepared by pharmacy will be flagged with “Paralytic Agent – Use with Caution”
- Restricted to ICU, CCU, NICU, Anaesthesia, ED, OR, PACU only.
- Auxiliary labels
- NMBA has a designated caution label attached to each dose and in the storage bin.
- NMBA is mainly used in Operation Theatre. In case it is outside the OT, orders for NMBA will be dispensed only on areas where ventilator is available.

An auxiliary label with the following **“WARNING: PARALYZING AGENT: PATIENT MUST BE VENTILATED”** is applied on the following:

Ampoules/Vials



IV Bags (Applied by Pharmacy)



IV Lines (Applied by Nursing)





Administration

- Ensure patient is intubated.
- Independent double check

Recommendation

- **Clear and accurate labeling** with double revising and rechecking the labeling with warning and high alert label.
- There should be a **regular training specifically for NMBs** to increase the awareness for this specific group of medicine, not only for OT staff, but for all medical professionals who might deal with NMBs.
- Use **neuromuscular blockers**” or **“paralyzing agents** while prescribing.
- Orient the staff about the **risk of serious errors** with these high-alert drugs.
- Generate training program and competency verification process for practitioners involved in preparing, dispensing, and administering neuromuscular blockers.





THANK YOU

