Neuromuscular Blockers: Safety Measures and Labeling Requirements

IMSN Neuromuscular Blocker Safety Interest Group

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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	Macarthys Laboratories Limited T\A Martindale Pharma	United Kingdom

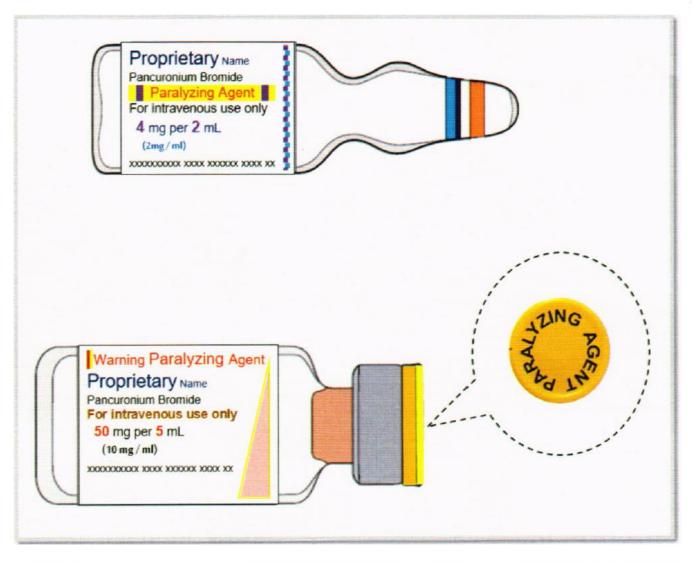
Circular

- Warning statement (Paralyzing agent)
- Implementation Date 01 January 2023

 الهيئة الصامة للضخاء والحواء
Saudi Food & Drug Authority (255) الموضوعة إضافة تحذير (Paralyzing Agent) على المستحضرات المسجلة (Neuromuscular blocking agents) من المجموعة العلاجية فم: ١٢١٨٥ / ١٢١٨٥ تابع: ٢١٤١٢ / ٢٦٢٢ السادة شركات الأدوية السادة وكلاء شركات الأدوية المحترمين السلام عليكم ورحمة الله وبركاته المحترمين انطلاقا من دور البيئة الرقابي لضمان سلامة استخدام المستحضرات الصيدلانية في مراحل ما بعد التسويق من خلال وضع الضوابط والإجراءات الاحترازية اللازمة. واشارة الى فرصة حدوث اخطاء دوانية قد تؤدي الى أعراض جانبية خطيرة نتيجة لاستخدام المستحضرات الدوانية المحتوية على المجموعة العلاجية (Neuromuscular Blocking Agents). عليه يجب على شركات الأدوية المصنعة للمستحضرات الدوانية المحتوية على المجموعة العلاجية المذكورة أعلاه اضافة تحذير (Paralyzing Agent) باللغة الإنجليزية على غلاف العبوة الخارجي والداخلي بشكل واضع. وفي حال كانت العبوة على شكل (Vial) فيضاف التعذير على الغطاء علماً بأنه سيتم العمل يهذا الإجراء اعتبارا من تابع ١ يناير ٢٠. ٣م. ولمزيد من المعلومات يرجى التواصل مع إدارة الأخطاء الدوانية عن طريق البريد الالكتروني (Med.drug@sfda.gov.sa). أملين د. عادل بن عبدالله الهرف فه جه : على جين ليشعري יישאל הענקעלי 1831 (בעלה - "אינולה לבילקט לבהבל, לאנינט ירגט לבלה בעיט אוציו 1857, אלהה 1877 אינו אלויט אוצוייי איני אלוס

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Circular



Labeling Requirements

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

Neuromuscular Blocking and Paralyzing Agents All injectable neuromuscular blocking agents and paralyzing agents must be packaged in vials with a cautionary statement printed on the ferrules and cap overseals. Both the container cap ferrule and the cap overseal must stand out in black or white print (whichever provides the greatest color contrast with the ferrule or cap color) the words: "Warning: Paralyzing Agent" or "Paralyzing Agent" (depending on the size of the closure system). Alternatively, the overseal may be transparent and without words, allowing for visualization of the warning labeling on the

- Ampules containers are not recommended for paralyzing agents since they tend to be very small for the warning to be visible and usually ampules have similarity with other ampules,



Guidance for Graphic Design of Medication Packaging (Version no.3.1). Nov 2022, SFDA



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 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



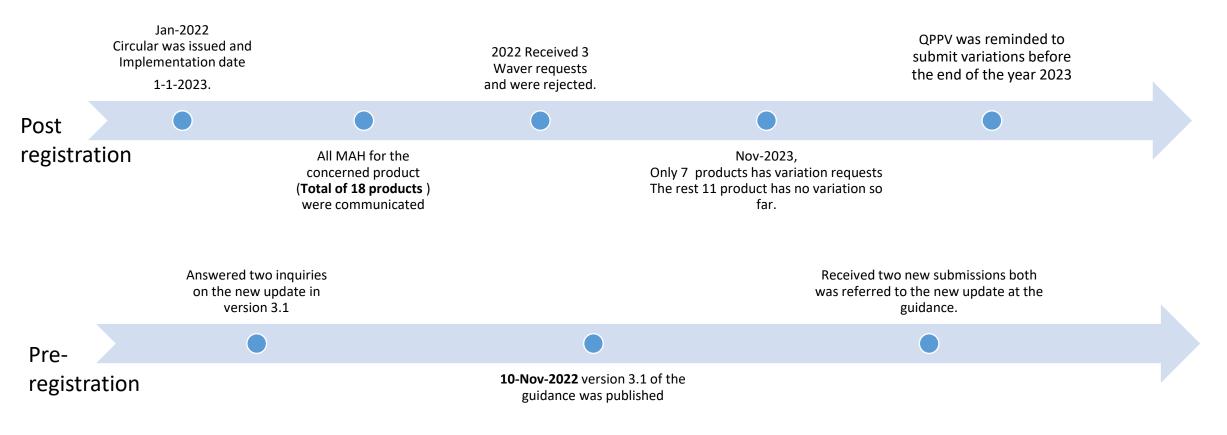
Effective Communication of Warnings

- "WARNING: CAUSES RESPIRATORY ARREST PATIENT MUST BE VENTILATED"
- "WARNING: PARALYZING AGENT CAUSES RESPIRATORY ARREST"
- "WARNING: CAUSES RESPIRATORY PARALYSIS PATIENT MUST BE VENTILATED"

ISMP. ISMP Medication Safety Alert! Acute Care. 2019;24(4):1-5. ISMP. ISMP Targeted Medication Safety Best Practices for Hospitals. ISMP; 2022



Timeline for Change



الهيئة الحامة للخذاء والحواء Saudi Food & Drug Authority

Reports?

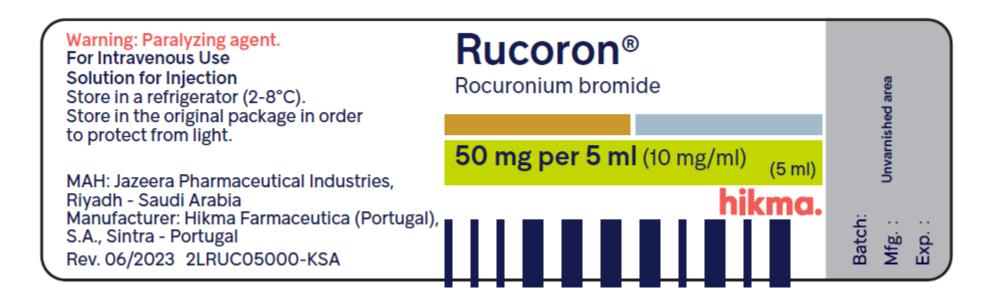


Rucoron (Rocuronium Bromide) 50mg/ 5mL (10 mg/mL) Injection — Strength Expression Report





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



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