



Potential impact of Bridion® on patient safety, surgical conditions and operating room costs

BRIDION® (Sugammadex):

C: Sugammadex. **I:** Reversal of rocuronium- or vecuronium-induced neuromuscular block (NMB). **D:** Use only by or under the supervision of an anesthetist. Use appropriate neuromuscular monitoring technique. Recommended dose depends on degree of NMB, not anesthesia procedure. **Adults:** Routine reversal of NMB: dose 4.0mg/kg body weight at 1-2 Post-Tetanic Counts (PTC); dose of 2.0mg/kg if spontaneous recovery until recovery of two stimulus responses (T2). **Immediate NMB reversal dose:** 16.0mg/kg. Immediate reversal of NMB after vecuronium-induced blockade not recommended. **Dosage on recurrence of NMB:** Initial 2mg/kg or 4mg/kg, then re-application of 4mg/kg recommended. Possible need for artificial respiration. After 2nd sugammadex dose, closely monitor patient. **Renal failure:** Not recommended for severely impaired renal function including dialysis (CrCl < 30ml/min). **Adipose patients:** Base sugammadex dose on actual body weight. **Liver failure:** Use with great caution in severe liver failure or in liver failure with coagulopathy. **Correct route of administration:** administer i.v. rapidly (within 10 sec), preferably once-only bolus in existing i.v. route. For further indications and the corresponding dosing, please refer to the full prescribing information. **CI:** Hypersensitivity to active substance/excipients. **Pr:** Artificial respiration required until sufficient spontaneous respiration obtained. Even after sufficient recovery from NMB, artificial respiration may be required due to other medications. If recurrence occurs after extubation, provide adequate artificial respiration. **Recurrence of NMB:** Lower doses than recommended may increase the risk of recurrence of NMB after initial reversal and should not be used. Not for reversal of block by non-steroidal neuromuscular blockers (e.g. succinylcholine or benzylisoquinoline-like substances). Not to reverse NMB by other steroidal neuromuscular blockers than rocuronium or vecuronium. **Anesthesia complications:** If NMB is reversed under continued anesthesia, additional doses of the anesthetic and/or opioid are required. Close monitoring of hemodynamic parameters during and after administration (bradycardias). In clinically significant bradycardia, immediately take appropriate emergency actions and administer an anticholinergic. **Effects on hemostasis:** Use cautiously in patients with anamnestic or therapeutic anticoagulation. **Hypersensitivity reactions:** Prepare and take necessary precautions for hypersensitivity reactions (including anaphylactic reactions). **DDI:** Displacement of toremifene and fusidic acid, complex formation with hormonal contraceptives (additionally use barrier-forming contraceptives). **In vitro:** influencing serum progesterone levels, pharmacodynamic interactions (prolongation of aPTT and PT) with vitamin K antagonists, unfractionated heparin, low molecular weight heparinoids, rivaroxaban, dabigatran. **P/L:** No use during pregnancy unless absolutely necessary. Not recommended during lactation. **UDE:** Common: cough, nausea, vomiting, attenuated therapeutic effect. **P:** Solution for injection in vials: 200mg/2ml, 500mg/5ml. **C: B. MAH:** MSD Merck Sharp & Dohme AG, Werftstrasse 4, 6005 Lucerne, Switzerland. (V4.0); CH-XBR-00005. Before prescribing, please consult the full prescribing information published on the homepage of Swissmedic (www.swissmedicinfo.ch). Copyright © 2022 Merck & Co., Inc., Rahway, NJ, USA and its affiliates. All rights reserved.

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Potential perioperative improvement with Bridion®

	Induction	Procedure	Recovery	PACU	ICU/Ward
Neuromuscular Block (NMB) and Deep NMB	<p>Sugammadex has been designed to reverse rocuronium-induced paralysis in a faster, more reliable, and better tolerated way when compared with neostigmine¹. Sugammadex can enable the routine use of deep NMB in various procedures as it can reverse the neuromuscular block in 2.7 minutes, on average, and minimize the potential adverse events of residual NMB.¹⁻⁵</p>				
Patient safety and comfort	<p>Rocuronium with Sugammadex showed to:</p> <ul style="list-style-type: none"> Have a lower incidence of myalgia and laryngoscopy resistance than succinylcholine^{6,b} Have a rapid onset of action^{7,8} Re-establish spontaneous ventilation earlier than succinylcholine⁸ 	<p>Less surgical complications with the deep NMB allowed by Rocuronium with Sugammadex compared with previous moderate NMB. The surgical conditions were evaluated by the surgeon using the four point King score.^{3,a}</p>	<p>Sugammadex is more effective than neostigmine in reducing the potential for residual blockade in the absence of objective neuromuscular monitoring¹⁶:</p> <ul style="list-style-type: none"> 96% of patients had TOF >0.9 at or before extubation with sugammadex vs 39.5% with neostigmine+ glycopyrrolate¹⁶ 4x more rapid to achieve TOF >0.9 (median time to achieve TOF >0.9: 2min with sugammadex vs 8 min with neostigmine)¹⁶ 	<p>Less postoperative pain during laparoscopies with deep NMB induced by rocuronium, compared with moderate NMB²</p> <p>48% less risk of postoperative nausea and vomiting with sugammadex vs neostigmine in reversing neuromuscular blockade^{1,e}</p> <p>Sugammadex has shown positive effects on the recovery of gastrointestinal motility (vs pyridostigmine + glycopyrrolate).^{13,f}</p>	<p>Sugammadex vs neostigmine:</p> <ul style="list-style-type: none"> 40% less adverse events¹ 84% less risks of bradycardia¹ 60% less risk of overall signs of postoperative residual paralysis, defined as¹: <ul style="list-style-type: none"> inability to perform 5-second head-lift test and general muscle weakness after extubation and at PACU discharge¹ amblyopia, asthenia, desaturation < 90%, transitory oxygen supplementation¹ respiratory distress, respiratory depression, postoperative respiratory complications¹
Surgical conditions	<p>Deep NMB induced by Rocuronium showed:</p> <ul style="list-style-type: none"> Better surgical conditions during laparoscopies and endolaryngeal surgery^{2,10} Improved image quality during endovascular coiling and no need for rescue muscle relaxant⁴ Facilitated use of low-pressure pneumoperitoneum in laparoscopic procedures² 				
Time and Costs	<p>The median time to reverse deep NMB with Sugammadex was 16.8 x faster than with neostigmine (3min vs 49 min)^{1,c}</p>	<p>QUANTITATIVE MONITORING IS RECOMMENDED for patients who receive NMBAs during anaesthesia^{14,15}</p> <p>When the recommendations of TOF >0.9 before extubation is strictly followed, sugammadex vs neostigmine to reverse NMB showed to:</p> <ul style="list-style-type: none"> save, on average, 62 minutes per operating room per day^{9,d} lead to, on average, 2.2 more procedures per operating room, per month^{9,d} 		<p>Introducing sugammadex to the routine reversal of neuromuscular blockade in Spanish hospitals could save €57.1 million annually by avoiding pulmonary complications.¹¹</p> <p>Patients who received a nondepolarizing neuromuscular blocking drug and had a quantitative monitoring (TOF ≥ 0.9 before extubation) had a shorter hospitalization time (on average 1 day less) compared to patients without quantitative monitoring.¹²</p>	

1. I. Hristovska AM, et al. Efficacy and safety of sugammadex versus neostigmine in reversing neuromuscular blockade in adults. Cochrane Database Syst Rev. 2017 Aug 14;8(8):CD012763. 2. Bruinjes MH, et al. Deep neuromuscular block to optimize surgical space conditions during laparoscopic surgery: a systematic review and meta-analysis. Br J Anaesth. 2017 Jun 1;118(6):834-842. 3. Fuchs-Buder T, et al. Deep neuromuscular blockade improves surgical conditions during gastric bypass surgery for morbid obesity: A randomised controlled trial. Eur J Anaesthesiol. 2019 Jul;36(7):486-493. 4. Kim BY, et al. Deep neuromuscular block improves angiographic image quality during endovascular coiling of unruptured cerebral aneurysms: a randomized clinical trial. J Neurointerv Surg. 2020 Nov;12(11):1137-1141. 5. Jones RK, et al. Reversal of profound rocuronium-induced blockade with sugammadex: a randomized comparison with neostigmine. Anesthesiology 2008;109(5):816-24. 6. Stourac P, et al. Low-Dose or High-Dose Rocuronium Reversed with Neostigmine or Sugammadex for Cesarean Delivery Anesthesia: A Randomized Controlled Noninferiority Trial of Time to Tracheal Intubation and Extubation. Anesth Analg. 2016 May;122(5):1536-45. 7. Sinclair RCF, et al. Rapid sequence induction. Continuing Education in Anaesthesia Critical Care & Pain. 2005;5(2):45-48. 8. Sørensen MK, et al. Rapid sequence induction and intubation with rocuronium-sugammadex compared with succinylcholine: a randomized trial. Br J Anaesth. 2012 Apr;108(4):682-9. 9. Insinga RP, et al. A discrete event simulation model of clinical and operating room efficiency outcomes of sugammadex versus neostigmine for neuromuscular block reversal in Canada. BMC Anesthesiol. 2016 Nov 16;16(1):114. 10. Laosuwan P, et al. Deep neuromuscular blockade for endolaryngeal procedures: A multicenter randomized study. Laryngoscope. 2020 Feb;130(2):437-441. 11. Martínez-Ubieto J, et al. Economic impact of improving patient safety using Sugammadex for routine reversal of neuromuscular blockade in Spain. BMC Anesthesiol. 2021 Feb 16;21(1):55. 12. Weigel WA, et al. Quantitative Neuromuscular Monitoring in a Clinical Practice: A Professional Practice Change Initiative. Anesthesiology. 2022 Feb 21. 13. An J, et al. Neuromuscular blockade reversal with sugammadex versus pyridostigmine/glycopyrrolate in laparoscopic cholecystectomy: a randomized trial of effects on postoperative gastrointestinal motility. Korean J Anesthesiol. 2020 Apr;73(2):137-144. 14. Dutt M, et al. Neuromuscular monitoring: an update. Rom J Anaesth Intensive Care. 2018 Apr;25(1):55-60. 15. Lien CA, et al. Current recommendations for monitoring depth of neuromuscular blockade. Curr Opin Anaesthesiol. 2014 Dec;27(6):616-22. 16. Sabo D, et al. Residual Neuromuscular Blockade at Extubation: A Randomized Comparison of Sugammadex and Neostigmine Reversal of Rocuronium-Induced Blockade in Patients Undergoing Abdominal Surgery. J. Anesth Clin Res. 2011;2:140.

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NMBA: Neuromuscular blocking agent; NMB: Neuromuscular block; PACU: postanesthesia care unit; RSI: Rapid sequence induction; TOF: Train of Four. a. in gastric bypass surgery b. Secondary endpoint. The primary endpoint of this study was the mean time to tracheal intubation. It was 2.9 seconds longer in the ROC group (95% confidence interval, -5.3 to 11.2 seconds), noninferior compared with the SUX group. c. from post-tetanic count (PTC) 1 to 5 to TOFR > 0.9 (MD 45.78 minutes, 95% CI 39.41 to 52.15) d. when waiting for a TOF > 0.9 before extubation is strictly followed. e. RR 0.52, 95% CI 0.28 to 0.97; I2 = 0%; six studies, n = 389; NNTB 16; GRADE: low quality f. in laparoscopic cholecystectomy

