SUGAMMADEX

Clinical Use Protocol

In delivering

Predictable, Complete and Rapid

reversal from any level of
neuromuscular blockade (NMB)

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Anaesthesiologist

Contents

This is only an advisory from the Expert Panel based on current information and is only applicable for Malaysia. Clinical judgement is still of paramount importance for the reversal of neuromuscular blockade. Sugammadex is specific for reversal of neuromuscular blockade with rocuronium.

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Type of patient for Sugammadex

- Elderly patients (more than 65 years of age)
- COPD / Bronchial hyperreactivity / Asthma / End stage lung disease
- Mild or moderate renal failure (Creatinine clearance more than 30 ml/min)
- Patients with IHD, tachyarrhythmias, valvular heart disease undergoing major surgery
- Known or suspected patients with obstructive sleep apnoea (OSA)
- Obese patients (BMI > 30) with or without OSA symptoms for general surgery requiring use of muscle relaxants
- Patients with neuromuscular disease for general surgery requiring use of muscle relaxants (e.g. myasthenia gravis, muscular dystrophies)
- Contraindication to succinylcholine
  a. Burned patient
  b. Patients with myopathy
  c. Patients with syndrome of lower motor neuron (paraplegia/ tetraplegia)

Technical use of Sugammadex

- Major and problematic shared airway surgeries
- Prolonged surgery (>4 hours)
- In surgeries that end prematurely, following rocuronium administration to facilitate timely reversal
- Surgeries requiring deep neuromuscular blockade intra-operatively (e.g. laparoscopy, oesophagectomy, radical prostatectomy with bladder reconstruction, aneurysm repair surgeries)
- Can't intubate and can't ventilate after induction of anesthesia
  a. For reversal of difficult airway (Unanticipated and / or Anticipated difficult airway)
- Reversal of residual neuromuscular block after given atropine / neostigmine
- For surgeries of the spine when Motor Evoke potentials are used as intraoperative neuro-monitoring, and paralysis is still profound
- Electroconvulsive therapy (ECT) procedures where suxamethonium is contraindicated (eg. pseudocholinesterase deficiency; atypical cholinesterase)

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General Guidelines for Sugammadex

- Neuromuscular monitoring (Qualitative or Quantitative) is strongly recommended during surgery
- Dosage for sugammadex should be according to guidelines (*latest prescribing information)
  - If TOF count of 2 present: sugammadex 2 mg/kg
  - If TOF zero and post-tetanic count (at least 1–2) present: sugammadex 4 mg/kg
  - If immediate reversal is required after intubating dose of rocuronium: sugammadex 16 mg/kg
- Repeat administration of rocuronium / vecuronium is not recommended within 24 hours after administration of sugammadex. Advise to use other neuromuscular blocking agents if patients need reintubation / re-operation
- Patients should be observed for signs of inadequate reversal in the post-operative period (sensation of dyspnoea, muscle weakness, oxygen desaturation, etc)

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Selected safety information on Sugammadex

- **Indications:** BRIDION is indicated for the reversal of neuromuscular blockade induced by rocuronium or vecuronium. For the peadiatric population, BRIDION is only recommended for routine reversal of rocuronium induced blockade in children and adolescents.
- **Dosage and Administration:** BRIDION should be administered only by, or under the supervision of, an anesthetist. Neuromuscular monitoring is recommended during recovery of neuromuscular blockade. Ventilatory support is mandatory for patients until adequate spontaneous respiration is restored following reversal. Even if recovery from neuromuscular blockade is complete, other medicinal products used in the peri- and postoperative period could depress respiratory function and, therefore, ventilatory support might still be required. If neuromuscular blockade is required within 24 hours of BRIDION administration, a nonsteroidal neuromuscular blocking agent should be used instead of rocuronium or vecuronium.
- **Contraindications:** BRIDION is contraindicated in patients hypersensitive to sugammadex or any of its excipients.

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- **Precautions and Drug Interactions:** BRIDION is not recommended in patients with severe renal impairment (including patients requiring dialysis [CrCl < 30 mL/min]). Studies in patients with hepatic impairment have not been conducted and, therefore, patients with severe hepatic impairment should be treated with great caution. Caution should be exercised when administering BRIDION to pregnant women as no clinical data on exposed pregnancies are available. BRIDION has not been investigated in patients receiving rocuronium or vecuronium in the ICU setting.

- **Side Effects:** The most commonly reported adverse reactions were dysgeusia (metal or bitter taste) and anesthetic complications (eg, movement, coughing, grimacing, or suckling on the endotracheal tube). In patients treated with BRIDION, a few cases of awareness were reported. The relationship to BRIDION was uncertain. Drug hypersensitivity reactions: Hypersensitivity reactions have occurred in some patients and volunteers. In clinical trials these reactions were reported uncommonly and for postmarketing reports the frequency is unknown. These reactions varied from isolated skin reactions to serious systemic reactions (ie, anaphylaxis, anaphylactic shock) and have occurred in patients with no prior exposure to sugammadex. Symptoms associated with these reactions can include: flushing, urticaria, erythematous rash, (severe) hypotension, tachycardia and swelling of tongue and pharynx. Clinicians should be prepared for the possibility of allergic reactions and take the necessary precautions. In a trial of patients with a history of pulmonary complications, bronchospasm was reported in 2 patients and a causal relationship could not be fully excluded. Volunteer studies have demonstrated a slight (17% to 22%) and transient (< 30 minutes) prolongation of the PT/aPTT with BRIDION; however, clinical studies have demonstrated no clinically relevant effect on peri- or postoperative bleeding complications with BRIDION alone or in combination with anticoagulants. Preclinical data suggest that clinically significant drug interactions are unlikely with the possible exceptions of teremifene, flucloxacillin, fisidic acid and hormonal contraceptives.

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