References


Pediatric Patients:


4 Masato Morita. Efficacy and Safety of Sugammadex in Infants and Neonates Weighing Less than 4 kg Undergoing Open Abdominal Surgery, Aris Kosei Hospital, Aichi, Japan


Others:

1 Bond LH. Cyclodextrins and the Emergence of Sugammadex. Anaesthesia, 2009; 64(suppl.1): 31-37.


4 Kopman AF, Eikermann M. Antagonism of non-depolarising neuromuscular block: current practice; Anaesthesia, 2009; 64(suppl.1): 22-30.

5 Mirakhur RK. Sugammadex in clinical practice. Anaesthesia, 2009; 64(suppl.1): 45-54.


This guideline booklet is made possible by an unrestricted educational grant from MSD.
This is only an advisory from the Expert Panel based on current information and is only applicable for Malaysia. Neuromuscular monitoring and clinical judgement is still of paramount importance for the reversal of neuromuscular blockade. Sugammadex is specific for reversal of neuromuscular blockade with rocuronium.
Special Patient Populations

- 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. Patient with burns
  - b. Patients with myopathy
  - c. Patients with syndrome of lower motor neuron disease (paraplegia/tetraplegia)
  - d. Anaphylaxis to succinylcholine
  - e. Malignant Hyperpyrexia (MH)
  - f. Atypical cholinesterase
- Paediatric population patients
  - a. Can be used in 2 years and above
  - b. No strong evidence in neonates

Obstetric patients
Rocuronium and Sugammadex may be used instead of succinylcholine for neuromuscular block in obstetric patients undergoing Caesarean section.

Special Situations

- Major and problematic shared airway surgeries
- Prolonged surgery (>4 hours)
- In surgery that terminate 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)
- As rescue therapy in “cannot intubate, cannot ventilate” situation after induction of anesthesia when rocuronium was used. For reversal of difficult airway (Unanticipated and / or Anticipated difficult airway).
  Caution: Return of muscle function does not guarantee the return of spontaneous breathing. It is recommended that precalculated dose of sugammadex must be available in the theatre for induction of suspected difficult airway with rocuronium.
- Reversal of residual neuromuscular blockade after given atropine / neostigmine in intubated or extubated patients
- For spine surgeries when Motor Evoke potentials are used as intraoperative neuro-monitoring, and paralysis is still profound
- Electroconvulsive therapy (ECT) procedures where suxamethonium is contraindicated (e.g. pseudocholinesterase deficiency; atypical cholinesterase)
General Guidelines

- Neuromuscular junction monitoring (Qualitative or Quantitative) is strongly recommended during surgery.
- Recommended Dosage for sugammadex should be according to guidelines (*latest prescribing information).

<table>
<thead>
<tr>
<th>Situation</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Emergency situations “cannot intubate, cannot ventilate”</td>
<td>16mg/kg</td>
</tr>
<tr>
<td>Reversal of ‘deep’ block (defined as a post-tetanic count of two twitches)</td>
<td>4mg/kg</td>
</tr>
<tr>
<td>Reversal of ‘shallow’ block (defined as two twitches of a train of four)</td>
<td>2mg/kg</td>
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</tbody>
</table>

- Repeat administration of rocuronium / vecuronium is not recommended within 24 hours after administration of sugammadex. Advised 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).

In obese patients, Adjusted Body Weight (BW) is recommended:

Adjusted Body Weight (kg) = Ideal Body Weight (kg) + 0.4 [Total Body Weight (kg) – Ideal Body Weight (kg)]

Selected Safety Information

Indications: BRIDION is indicated for the reversal of neuromuscular blockade induced by rocuronium or vecuronium. For the paediatric 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.

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.
Selected Safety Information

Side Effects: The most commonly reported adverse reactions were dysesthesia (metal or bitter taste) and anesthetic complications (eg, movement, coughing, grimacing, or sucking 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.

Deep Neuromuscular Blockade:

Efficacy and Safety of Sugammadex:

Obesity:

Obstetrics and Gynaecology:

References