### **MONOGRAPH**

# **Sugammadex**

Scope (Staff):	Medical, Pharmacy, Nursing, Anaesthetic Technicians	
Scope (Area):	All Clinical Areas	

# **Child Safe Organisation Statement of Commitment**

CAHS commits to being a child safe organisation by applying the National Principles for Child Safe Organisations. This is a commitment to a strong culture supported by robust policies and procedures to reduce the likelihood of harm to children and young people.

QUICKLINKS						
<u>Dosage/Dosage</u> Adjustments	<u>Administration</u>	Compatibility	Monitoring			

### **DRUG CLASS**

### Neuromuscular blockade reversal<sup>1</sup>

Sugammadex is a modified gamma cyclodextrin that forms a complex with the neuromuscular blocking agents, rocuronium and vecuronium. This results in a reduction in the amount of neuromuscular blocking agent available to bind to nicotinic cholinergic receptors in the neuromuscular junction, and the neuromuscular blockade induced by rocuronium or vecuronium is thereby reversed.

### **INDICATIONS AND RESTRICTIONS**

 Restricted to prescribing by anaesthetists to reverse the neuromuscular blockade induced by rocuronium and vecuronium.<sup>3</sup>

#### **CONTRAINDICATIONS**

Hypersensitivity to sugammadex or any component of the formulation.

### **PRECAUTIONS**

- Manufacturer discourages use when Creatinine clearance (CrCl) <30 mL/minute (limited data).<sup>1</sup>
- Bradycardia: Marked bradycardia and bradycardia with cardiac arrest have been reported, usually within minutes after administration. Monitor closely for hemodynamic changes during

and after reversal of neuromuscular blockade; use appropriate pharmacologic treatment (e.g., atropine) if significant bradycardia occurs.<sup>2</sup>

- Hypersensitivity: Serious hypersensitivity reactions (including anaphylaxis and anaphylactic shock) have been reported (uncommonly). May occur in patients without prior exposure to sugammadex.<sup>2</sup>
- Recurrence of neuromuscular blockade.<sup>2</sup>
- Use caution in patients with cardiovascular disease.<sup>2</sup>
- Use caution in patients with hepatic impairment, especially in the presence of coagulopathy or severe oedema.<sup>2</sup>
- Use caution in patients with impaired haemostasis (e.g. coagulopathies, severe liver impairment, concurrent use of anticoagulants).<sup>2</sup>
- Sugammadex theoretically reduces the effectiveness of hormonal contraception<sup>1</sup>

### **FORMULATIONS**

Listed below are products available at PCH, other formulations may be available, check with pharmacy if required:

- 200mg/2mL vial
- 500mg/5mL vial

Imprest location: Formulary One

### **DOSAGE & DOSAGE ADJUSTMENTS**

**Neonates: Refer to Neonatal Medication Protocols** 

Calculate dose based on actual body weight<sup>2</sup>

Routine reversal of <u>rocuronium</u> –induced moderate blockade Children < 2 years – IV bolus:

2mg/kg or 4mg/kg as a single dose over 10 seconds

Routine reversal of <u>rocuronium- or vecuronium-induced blockade</u><sup>2</sup> Child >2 years – IV bolus:

- 4 mg/kg given within 10 seconds if recovery has reached 1–2 post-tetanic counts.<sup>1</sup>
- 2 mg/kg given within 10 seconds if recovery has occurred up to reappearance of T<sub>2</sub>.<sup>1</sup>

### **Renal impairment:**

Children ≥2 years and Adolescents:

CrCl <30 mL/minute/1.73 m<sup>2</sup>: Use is not recommended.<sup>2</sup> e GFR calculator

Dialysis - use is not recommended.<sup>2</sup>

## **Hepatic impairment:**

# Children ≥2 years and Adolescents:

• There are no dosage adjustments provided in the manufacturer's labelling (has not been studied); use with caution, particularly if accompanied by coagulopathy or severe oedema.<sup>2</sup>

### **ADMINISTRATION**

- Administer as a rapid bolus injection within 10 seconds.<sup>4</sup>
- To increase the accuracy of dosing in the paediatric population, sugammadex 100 mg/mL may be diluted to a concentration of 10 mg/mL using 0.9% Sodium Chloride Injection.<sup>5</sup>
- Re-administration with neuromuscular blocking agents (NMBA) after reversal with sugammadex: If re-administration of rocuronium or vecuronium is required after reversal with sugammadex (up to 4 mg/kg), the following waiting times are recommended:<sup>6</sup>

In patients with normal renal function (creatinine clearance >80mL/min):6

Minimum waiting time	NMBA and dose to be administered	
5 minutes	1.2mg/kg rocuronium	
4 hours	0.6mg/kg rocuronium OR 0.1mg/kg vecuronium	

When rocuronium 1.2 mg/kg is administered within 30 minutes after reversal with sugammadex, the onset of neuromuscular blockade may be delayed up to approximately 4 minutes and the duration of neuromuscular blockade may be shortened up to approximately 15 minutes.<sup>6</sup>

## **COMPATIBILITY (LIST IS NOT EXHAUSTIVE)**

Compatible fluids: Sodium chloride 0.9%.4

## Compatible at Y-site:

Gelofusine, glucose 5%, glucose 2.5% in sodium chloride 0.45%, glucose 5% in sodium chloride 0.9%, Hartmann's, Plasma-Lyte 148 via Y-site, Ringers, sodium chloride 0.9%.

### Incompatible fluids: No information.4

Only commonly used drugs are listed below. This is not a complete list of incompatible drugs. Compatibilities of IV drugs must be checked when two or more drugs are given concurrently.

**INCOMPATIBLE drugs:** Amiodarone, dobutamine, ondansetron, protamine, ranitidine, verapamil.<sup>4</sup>

### **MONITORING**

Maintain standard monitoring of haemodynamics changes and ventilation from administration of sugammadex to recovery of neuromuscular function and extubation of the patient in accordance to the Australian and New Zealand College of Anaesthetists (ANZCA) guidelines:

- Pulse Oximetry.<sup>7</sup>
- Electrocardiography (ECG.)<sup>7</sup>
- Capnography.<sup>7</sup>
- Blood pressure.<sup>7</sup>
- Neuromuscular blockade.<sup>7</sup>

### **ADVERSE EFFECTS**

Common (>1%) postoperative nausea/vomiting.1

**Infrequent (0.1–1%)** hypersensitivity reactions (including anaphylaxis) usually soon after the first dose<sup>1</sup>

Rare (<0.1%) bradycardia.1

### **STORAGE**

Vial: store below 30 °C. Do not freeze. Protect from light. Use within 5 days if not stored protected from light.<sup>6</sup>

# INTERACTIONS

This medication may interact with other medications; consult PCH approved references (e.g. Clinical Pharmacology), a clinical pharmacist or PCH Medicines Information Service on extension 63546 for more information.

\*\*Please note: The information contained in this guideline is to assist with the preparation and administration of **sugammadex**. Any variations to the doses recommended should be clarified with the prescriber prior to administration\*\*

### References

- 1. Australian Medicines Handbook (AMH) <a href="https://amhonline-amh-net-au.pklibresources.health.wa.gov.au/chapters/anaesthetics/other-agents-anaesthesia/drugs-reversing-neuromuscular-blockade/sugammadex?menu=hints">https://amhonline-amh-net-au.pklibresources.health.wa.gov.au/chapters/anaesthetics/other-agents-anaesthesia/drugs-reversing-neuromuscular-blockade/sugammadex?menu=hints</a>
- 2. Up-to-date <a href="https://www-uptodate-com.pklibresources.health.wa.gov.au/contents/sugammadex-pediatric-drug-information?sectionName=Pediatric&topicId=107775&search=sugammadex&usage\_type=pa\_nel&anchor=F46146793&source=panel\_search\_result&selectedTitle=2~56&kp\_tab=drug\_pe\_diatric&display\_rank=1&showDrugLabel=true#F46146793
- 3. Formulary ONE https://formulary.hdwa.health.wa.gov.au//SpecialtyEntry/Details/1501?specialtyId=3
- 4. Australian Injectable Drugs Handbook. 8<sup>th</sup> Edition <a href="https://aidh-hcn-com-au.pklibresources.health.wa.gov.au/browse/s/sugammadex">https://aidh-hcn-com-au.pklibresources.health.wa.gov.au/browse/s/sugammadex</a>

- 5. Clinical pharmacology https://www-clinicalkeycom.pklibresources.health.wa.gov.au/pharmacology/monograph/3621
- 6. 6 MIMS on Line Bridion® Product Information https://www-mimsonline-comau.pklibresources.health.wa.gov.au/Search/FullPI.aspx?ModuleName=Product%20Info&sear chKeyword=sugammadex&PreviousPage=~/Search/QuickSearch.aspx&SearchType=&ID=8 2180001 2
- 7. Guidelines on monitoring during anaesthesia Background paper PG18(A)BP
- 8. PG18(A)-Guideline-on-monitoring-during-anaesthesia.pdf (anzca.edu.au)

This document can be made available in alternative formats on request for a person with a disability.

File Path:	W:\Safety & Quality\CAHS\CLOVERS MEDICAL Pharmacy\Procedures Protocols and Guidelines\Medication Monographs\_Word\PCH.MED.Sugammadex.docx			
<b>Document Owner:</b>	Chief Pharmacist			
Reviewer / Team:	Senior Pharmacist, PCC Consultant, Consultant Anaesthetist, Consultant Anaesthetist			
Date First Issued:	Dec 2018	Last Reviewed:	Dec 2021	
Amendment Dates:	Jul 2022	Next Review Date:	Jun 2025	
Approved by:	Medication Safety Committee	Date:	Jun 2022	
Endorsed by:	Drug & Therapeutics Committee	Date:	Jul 2022	
Standards Applicable:	NSQHS Standards: OOO NSMHS: N/A Child Safe Standards: N/A			

Printed or personally saved electronic copies of this document are considered uncontrolled



# Healthy kids, healthy communities

Excellence Collaboration Accountability

Respect

Neonatology | Community Health | Mental Health | Perth Children's Hospital