BRIDION® 100 MG/ML SOLUTION FOR INJECTION
Sugammadex

PRESCRIBING INFORMATION
Refer to Summary of Product Characteristics (SmPC) before prescribing

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to MSD UK (Tel: 0208 1548000).
By clicking the above link you will leave the MSD website and be taken to the MHRA website.

PRESENTATION
Vials of 200mg (2 ml) or 500mg (5 ml).

USES
Reversal of rocuronium (ROC) or vecuronium (VEC) induced neuromuscular (NM) block in adults. For routine reversal of ROC-induced block in children and adolescents aged 2 to 17 years.

DOSAGE AND ADMINISTRATION
I.V. as a single bolus injection administered rapidly (within 10 seconds) into an existing I.V. line, by/under the supervision of an anaesthetist.
Use appropriate technique to monitor recovery of NM block. Dose depends on the level of block to be reversed, not the anaesthetic regimen.
Adults:
Routine reversal following ROC- or VEC-induced block:
- 4 mg/kg if recovery has reached at least 1-2 post-tetanic counts (PTC) following ROC- or VEC-induced block. Median recovery time (T_4/T_1 = 0.9) ≅ 3 minutes.
- 2 mg/kg if recovery has occurred up to at least T_2 following ROC- or VEC-induced block.
  Median recovery time (T_4/T_1 = 0.9) ≅ 2 minutes.

Median recovery time (T_4/T_1= 0.9) is slightly faster with ROC- than VEC-induced block.
Immediate reversal of ROC-induced block: 16 mg/kg. Median recovery time (T_4/T_1 = 0.9) ≅ 1.5 minutes when 16 mg/kg is given 3 minutes after a bolus dose of 1.2 mg/kg ROC. Not recommended for immediate reversal of VEC-induced block.
Re-administration of sugammadex: For post-operative recurrence of block after an initial dose of 2 mg/kg or 4 mg/kg, a repeat dose of 4 mg/kg is recommended. Monitor the patient closely to ascertain sustained return of neuromuscular function.
Re-administration of ROC or VEC after up to 4 mg/kg sugammadex: wait 5 minutes before re-use of 1.2 mg/kg ROC; wait 4 hours before re-use of 0.6 mg/kg ROC or 0.1 mg/kg VEC. Onset of NM block may be prolonged and duration of NM block may be shortened when ROC 1.2 mg/kg administered within 30 minutes of sugammadex use. After immediate reversal with 16 mg/kg sugammadex, a waiting time of 24 hours is recommended.
Special populations:
Renal impairment: For mild and moderate renal impairment use adult dose. Wait 24 hours after routine sugammadex reversal before re-use of 0.6 mg/kg ROC or 0.1 mg/kg VEC. Wait 24 hours after immediate reversal before re-administration of ROC or VEC. Not recommended in severe renal impairment (including patients requiring dialysis). Elderly: Use adult dose although recovery times are slower.
Obese: Adult dose based on actual body weight.
Hepatic impairment: Caution in patients with severe hepatic impairment, or impairment with coagulopathy.
Children and adolescents (2-17 years): 2 mg/kg for **routine** reversal of ROC-induced block at T_2. Not recommended in other routine reversal situations. Not recommended for **immediate** reversal. May be diluted for accuracy of dose.
Term newborn infants and infants: Not recommended.

CONTRA-INDICATIONS
Hypersensitivity to sugammadex or to any excipients.

PRECAUTIONS
Ventilatory support is mandatory for patients until adequate spontaneous respiration is restored following reversal of block. Should block reoccur following extubation, adequate ventilation should be provided. The use of lower than recommended doses may lead to an increased risk of recurrence of block after initial reversal. Caution should be exercised when considering the use of sugammadex in patients receiving anticoagulation for a pre-existing or co-morbid condition. An increased risk of bleeding cannot be excluded in patients: with hereditary vitamin K dependent clotting factor deficiencies; with pre-existing coagulopathies; on coumarin derivatives and at an INR above 3.5; using anticoagulants who receive a dose of 16mg/kg sugammadex. If neuromuscular block is required before the recommended waiting time has passed, a **nonsteroidal**

neuromuscular blocking agent should be used. If neuromuscular block is reversed, while anaesthesia is continued, additional doses of anaesthetic and/or opioid should be given as clinically indicated. Marked bradycardia and bradycardia with cardiac arrest have been observed within minutes after administration; closely monitor patients for haemodynamic changes during and after reversal. Treat with anti-cholinergic agents such as atropine if clinically significant bradycardia is observed. Sugammadex has not been investigated in patients receiving ROC or VEC in the ICU setting.

Do not use sugammadex to reverse block induced by **nonsteroidal** blockers such as succinylcholine or benzylisoquinolinium compounds, or **steroidal** blockers other than ROC or VEC. Conditions associated with prolonged circulation time such as cardiovascular disease, old age, or oedematous state may cause longer recovery times. Be prepared for possible drug hypersensitivity reactions. This medicinal product contains up to 9.7 mg sodium per mL, equivalent to 0.5 % of the WHO recommended maximum daily intake of 2 g sodium for an adult.

Drug interactions: Toremifene and fusidic acid may displace rocuronium or vecuronium from sugammadex and delay recovery (no clinically relevant capturing interactions are expected). Interaction of sugammadex with hormonal contraceptives may lead to a decrease in progestogen exposure equivalent to one missed daily dose of oral contraceptive (a clinically relevant capturing interaction could not be excluded, no displacement interactions are expected). In general sugammadex does not interfere with laboratory tests, with the possible exception of the serum progesterone assay where interference is observed at sugammadex plasma concentrations of 100 μg/ml. In a study in volunteers,doses of 4 mg/kg and 16 mg/kg sugammadex resulted in maximum mean prolongations of the activated partial thromboplastin time by 17% and 22% respectively and prothrombin time by 11% and 22% respectively. These were of short duration (≤ 30 minutes). In *in vitro* experiments a pharmacodynamic interaction was noted with vitamin K antagonists, unfractionated heparin, low molecular weight heparinoids, rivaroxaban and dabigatran.

Pregnancy and Lactation: Caution in pregnant women. Clinical consideration must be given whether to discontinue breast-feeding or to discontinue/abstain from sugammadex-therapy . The effects on human fertility have not been investigated.

SIDE EFFECTS

Refer to Summary of Product Characteristics for complete information on side effects

Common (> 1/100 to < 1/10): Bucking against the endotracheal tube, coughing, arousal reaction during surgery, spontaneous breathing, movement of limbs or body, grimacing, or suckling on the endotracheal tube; procedural hypotension, tachycardia, bradycardia, and increase in heart rate. Uncommon (≥ 1/1,000 to < 1/100): Drug hypersensitivity reactions, including anaphylaxis, have occurred in some patients and volunteers. In clinical trials these reactions were uncommon. For post-marketing reports the frequency is unknown. In clinical studies subjects treated with ROC or VEC, where sugammadex was administered, incidence of 0.20% was observed for recurrence of NM block as based on neuromuscular monitoring or clinical evidence.

OVERDOSE

No dose related adverse events nor serious adverse events were reported. Sugammadex can be removed using haemodialysis with a high flux filter.

HANDLING

See SmPC for details of compatibility with infusion solutions. Physical incompatibility has been reported with verapamil, ondansetron and ranitidine.

PACKAGE QUANTITIES AND BASIC NHS COST

10 vials of 2 ml: £596.40
10 vials of 5 ml: £1491.00

Marketing Authorisation Number

GB: PLGB 53095/0010
UK (NI): EU/1/08/466/001-002

Marketing Authorisation Holder

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Legal Category: POM

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