

ABBREVIATED PRESCRIBING INFORMATION

Bridion® ▼ 100 mg/ml solution for injection
sugammadex

Presentation: Vials of 200mg (2 ml) or 500mg (5 ml)

Use: Reversal of rocuronium (ROC) or vecuronium (VEC) induced neuromuscular (NM) block in adults. For routine reversal of ROC-induced block in children and adolescents.

Dosage and Administration: I.V. as a single bolus injection administered rapidly (within 10 seconds) directly into a vein or 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). Median recovery time ($T_4/T_1 = 0.9$) \approx 3 minutes
- 2 mg/kg if recovery has occurred up to at least T_2 following ROC- or VEC-induced block. Median recovery time ($T_4/T_1 = 0.9$) \approx 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 ($T_4/T_1 = 0.9$) \approx 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, repeat dose of 4 mg/kg is recommended. Following a second dose of sugammadex, monitor the patient closely to ascertain sustained return of neuromuscular function.

Re-administration of ROC or VEC after sugammadex: A waiting time of 24 hours should be taken into account.

Special populations:

Renal impairment: For mild and moderate renal impairment use adult dose. 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.

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.

Term newborn infants and infants: Not recommended.

Contraindications: Hypersensitivity to sugammadex or to any excipients.

Special warnings and precautions for use: 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.

To prevent recurrence of block, use the recommended doses for routine or immediate reversal. If re-administration of ROC or VEC is required a waiting time of 24 hours is recommended. If neuromuscular block is required before the recommended waiting time has passed, a **nonsteroidal neuromuscular blocking agent** should be used.

The use in patients with severe renal impairment is not recommended.

If neuromuscular block is reversed, while anaesthesia is continued, additional doses of anaesthetic and/or opioid should be given as clinically indicated.

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 allergic reactions. If more than 2.4 ml solution needs to be administered, this should be taken into consideration by patients on a controlled sodium diet. Sugammadex alone, or in combination with ROC or VEC, is not associated with QTc interval prolongation. During anaesthesia several medicinal products with the potential to prolong QTc (e.g. sevoflurane) are administered. The routine precautions for treating arrhythmia should be taken into consideration.

Interactions: Toremifene, flucloxacillin 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 progesterone exposure equivalent to one missed daily dose of oral contraceptive (no displacement interactions are expected). In general sugammadex does not interfere with laboratory tests, with the possible exception of the serum progesterone assay and some coagulation parameters (activated partial thromboplastin time prothrombin time, prothrombin time (international normalized ratio)).

Pregnancy and lactation: Caution in pregnant women. Sugammadex can be used during breast-feeding.

Side effects: Very common, dysgeusia (metal or bitter taste) mainly seen after doses of 32 mg/kg or higher. Common include anaesthetic complications, such as recurrence of block, movement of limbs or body or coughing during anaesthesia, grimacing, or suckling on the endotracheal tube. Other less common and rarely reported side effects are listed in the SmPC.

Overdose: No dose related adverse events nor serious adverse events were reported.

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

Pack sizes: 10 vials of 2 ml, or 10 vials of 5 ml.

Marketing Authorisation Number(S): EU/1/08/466/001-002

Marketing Authorisation Holder; N.V. Organon, Kloosterstraat 6, 5349 AB Oss, The Netherlands

Legal Category: Prescription Only Medicine.

NHS Price : 100mg/ml, 10 vials of 2ml £596.40
100mg/ml, 10 vials of 5ml £1491.00

Further information is available from Schering-Plough Ltd, Shire Park, Welwyn Garden City, Herts., AL7 1TW, UK.

Please refer to the full SmPC text before prescribing this product. Adverse events should be reported. Reporting forms and information can be found at www.yellowcard.gov.uk (UK) and www.imb.ie (Ireland). Adverse events with this product should also be reported to Schering-Plough Drug Safety Department on +44 (0)1707 363773.

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