TAILORED DOSING BASED ON DEPTH OF NMB

BRIDION can be used to reverse different levels of rocuronium- and vecuronium-induced blockade

MODERATE

If spontaneous recovery has reached the reappearance of the second twitch (T_2) in response to train-of-four (TOF) stimulation

Dose of BRIDION	Example patient weight	Calculated dose
2 mg/kg	At 87 kg	174 mg

DEEP

If spontaneous recovery of the twitch response has reached 1–2 posttetanic counts (PTCs), with no twitch responses to TOF

Dose of BRIDION	Example patient weight	Calculated dose
4 mg/kg	At 87 kg	348 mg

- BRIDION dosing should be based on actual body weight.

Indication

- BRIDION is indicated for the reversal of neuromuscular blockade induced by rocuronium bromide and vecuronium bromide in adults undergoing surgery.

Selected Safety Information

- BRIDION is contraindicated in patients with known hypersensitivity to sugammadex or any of its components. Hypersensitivity reactions that occurred varied from isolated skin reactions to serious systemic reactions (i.e., anaphylaxis, anaphylactic shock) and have occurred in patients with no prior exposure to sugammadex.

- Potentially serious hypersensitivity reactions, including anaphylaxis, have occurred in patients treated with BRIDION. In a clinical study, anaphylaxis occurred in 0.3% (n=1/299) of healthy volunteers treated with BRIDION. The most common hypersensitivity adverse reactions reported were nausea, pruritus and urticaria and showed a dose response relationship, occurring more frequently in the 16 mg/kg group compared to the 4 mg/kg and placebo groups. Observe patients for an appropriate period of time after administration and take the necessary precautions. Anaphylaxis has also been reported in the post-marketing setting. Clinical features in anaphylaxis reports have included dermatologic symptoms; hypotension often requiring the use of vasopressors; and prolonged hospitalization and/or the use of additional respiratory support until full recovery.

Selected Safety Information continued on next page.

Before administering BRIDION, please read the accompanying Prescribing Information.

bridion® (sugammadex) Injection 100 mg/mL*

*equivalent to 108.8 mg/mL sugammadex sodium

Additional dosing considerations

- The recommended dose of BRIDION does not depend on the anesthetic regimen.
- Administer BRIDION intravenously as a single bolus injection, which may be given over 10 seconds into an existing intravenous line. BRIDION has only been administered as a single bolus injection in clinical trials.
- Routine concomitant administration of an anticholinergic agent with BRIDION is not required. Treatment with anticholinergic agents, such as atropine, should be administered if clinically significant bradycardia is observed.

Drug compatibility

- May inject BRIDION into the intravenous line of a running infusion with the following intravenous solutions:
  - 0.9% sodium chloride
  - 5% dextrose
  - 0.45% sodium chloride and 2.5% dextrose
  - Ringer's solution
  - isolyte P with 5% dextrose
  - Ringer's lactate solution
  - 5% dextrose in 0.9% sodium chloride
- Ensure the infusion line is adequately flushed (eg, with 0.9% sodium chloride) between administration of BRIDION and other drugs.
- Do not mix BRIDION with other products except those listed above.
- BRIDION is physically incompatible with verapamil, ondansetron, and ranitidine.

Selected Safety Information

- Cases of marked bradycardia, some of which have resulted in cardiac arrest, have been observed within minutes after the administration of BRIDION. Monitor for hemodynamic changes and treat with anticholinergic agents, such as atropine, if clinically significant bradycardia is observed.
- Ventilatory support is mandatory for patients until adequate spontaneous respiration is restored and the ability to maintain a patent airway is assured.
- In clinical trials, a small number of patients experienced a delayed or minimal response to BRIDION. Monitor ventilation until recovery occurs.
- A minimum waiting time is necessary before re-administration of a steroidal neuromuscular blocking agent after administration of BRIDION.

Re-administration of Rocuronium or Vecuronium after Reversal (up to 4 mg/kg BRIDION)

Minimum Waiting Time	NMBA and Dose to be Administered
5 minutes	1.2 mg/kg rocuronium
4 hours	0.6 mg/kg rocuronium or 0.1 mg/kg vecuronium

If neuromuscular blockade is required before the recommended waiting time has elapsed, use a nonsteroidal neuromuscular blocking agent.

Selected Safety Information continued on next page.

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No dose adjustments of BRIDION are required in these special populations

- Geriatric patients with normal organ function.
  - Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection.
- Patients diagnosed with or who have a history of pulmonary complications.
- Patients diagnosed with or who have a history of cardiac disease (eg, patients with ischemic heart disease, chronic heart failure, or arrhythmia).
- Patients with mild to moderate renal impairment.
  - BRIDION is not recommended for use in patients with severe renal impairment, including those requiring dialysis.

Dosing BRIDION at 16 mg/kg

- **16 mg/kg** BRIDION is recommended if there is a clinical need to reverse NMB soon (approximately 3 minutes) after administration of a single dose of 1.2 mg/kg of rocuronium.
- The efficacy of the 16 mg/kg dose of BRIDION following administration of vecuronium has not been studied.

Selected Safety Information

- Due to the administration of BRIDION, certain drugs, including hormonal contraceptives, could become less effective due to a lowering of the (free) plasma concentrations. If an oral contraceptive is taken on the same day that BRIDION is administered, the patient must use an additional, non-hormonal contraceptive method or back-up method of contraception (such as condoms and spermicides) for the next 7 days. In the case of non-oral hormonal contraceptives, the patient must use an additional, non-hormonal contraceptive method or back-up method of contraception (such as condoms and spermicides) for the next 7 days.

- Recurrence of neuromuscular blockade may occur due to displacement of rocuronium or vecuronium from BRIDION by other drugs. Mechanical ventilation may be required. Stop the administration of the drug which caused displacement, if being administered by infusion.

- The use of lower than recommended doses of BRIDION may lead to an increased risk of recurrence of neuromuscular blockade and is not recommended.

Selected Safety Information continued on next page.

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BRIDION IS AVAILABLE AS CONVENIENT SINGLE-DOSE VIALS

- 2-mL single-dose vial 200 mg sugammadex
- NDC 0006-5423-12

- 5-mL single-dose vial 500 mg sugammadex
- NDC 0006-5425-15

Vials not shown at actual size.

- Each single-use dose contains a concentration of 100 mg/mL of sugammadex.
- Vials include a peel-off label that can be applied to the syringe.

Storage and handling

- Store at 25°C (77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) (see USP Controlled Room Temperature).
- Protect from light. When not protected from light, the vial should be used within 5 days.

Selected Safety Information

- BRIDION doses of up to 16 mg/kg were associated with increases in activated partial thromboplastin time and prothrombin time/international normalized ratio. Carefully monitor coagulation parameters in patients with known coagulopathies; being treated with therapeutic anticoagulation; receiving thromboprophylaxis drugs other than heparin and low molecular weight heparin; or receiving thromboprophylaxis drugs and who then receive a dose of 16 mg/kg sugammadex.

- BRIDION is not recommended for use in patients with severe renal impairment, including those requiring dialysis.

- The most common adverse reactions (reported in ≥10% of patients at a 2, 4, or 16 mg/kg BRIDION dose and higher than placebo rate) were vomiting (11%, 12%, or 15% versus placebo at 10%), pain (48%, 52%, or 36% versus placebo at 38%), nausea (23%, 26%, or 23% versus placebo at 23%), hypotension (4%, 5%, or 13% versus placebo at 4%), and headache (7%, 5%, or 10% versus placebo at 8%).

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