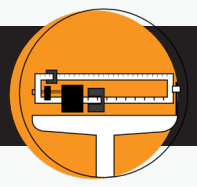
bridion® (sugammadex) Injection 100 mg/mL*

*equivalent to 108.8 mg/mL sugammadex sodium

How are you dosing BRIDION?

Indication

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

BRIDION dosing is based on:  **Actual body weight** +  **Depth of block**

Moderate Block	2 mg/kg dose

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

Deep Block	4 mg/kg dose

If spontaneous recovery of the twitch response has **reached 1-2 PTCs, no twitch responses** to TOF

Additional Dosing Considerations

- The recommended dose does not depend on the anesthetic regimen.
- Administer BRIDION intravenously as a single bolus injection. The bolus injection 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 co-administration of an anticholinergic agent is not required. Treatment with anticholinergic agents, such as atropine, should be administered if clinically significant bradycardia is observed.
- BRIDION 100 mg/mL may be diluted to a concentration of 10 mg/mL, using 0.9% sodium chloride injection, USP, to increase the accuracy of dosing in the pediatric population. Review the Prescribing Information (PI) for additional instructions on how to dilute BRIDION for pediatric use.

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.

Selected Safety Information continues below.

Dosing in Special Populations

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.
- Obese patients with a BMI ≥40 kg/m^2.

Dosing BRIDION at 16 mg/kg

- 16 mg/kg BRIDION is recommended if there is a clinical need to reverse neuromuscular blockade 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. Immediate reversal in pediatric patients has not been studied.

BRIDION is available as convenient single-dose vials

Each single-dose vial contains a concentration of 100 mg/mL of sugammadex, which is equivalent to 108.8 mg/mL sugammadex sodium.

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

Vials not shown at actual size.

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

Selected Safety Information *(continued)*

- 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.
- 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. Should neuromuscular blockade persist after BRIDION or recur following extubation, take appropriate steps to provide adequate ventilation.

Selected Safety Information continues on next page.

TOF, train-of-four; PTC, post-tetanic count; BMI, body mass index

Before administering BRIDION, please read the accompanying Prescribing Information.

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BRIDION Dosing Examples

This section offers guidance on selecting the appropriate BRIDION dose based on actual body weight and depth of block.[a]

	Moderate Block 2 mg/kg dose	Deep Block 4 mg/kg dose
	If spontaneous recovery has reached the **reappearance of the second twitch (T_2)** in response to TOF stimulation	If spontaneous recovery of the twitch response has **reached 1-2 PTCs, no twitch responses** to TOF
60 kg	120 mg	240 mg
110 kg	220 mg	440 mg

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.

Note: Features example patient weights only.

[a]BRIDION was studied vs neostigmine as a reversal agent for recovery from rocuronium- or vecuronium-induced moderate block in 189 patients with median weights of 72 kg and 76 kg, respectively. BRIDION was also studied in 157 patients with median weights of 81 kg and 84 kg for recovery from rocuronium- or vecuronium-induced deep block, respectively.

Selected Safety Information *(continued from page 1)*

- 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.

- Due to the administration of BRIDION, certain drugs, including hormonal contraceptives, could become less effective due to a lowering of the (free) plasma concentrations. Consider re-administration of the other drug, administration of a therapeutic equivalent drug, and/or non-pharmacological interventions as appropriate. 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. Also, when drugs which potentiate neuromuscular blockade are used in the post-operative phase, recurrence of neuromuscular blockade is possible.
- 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.
- BRIDION has not been studied for reversal following rocuronium or vecuronium administration in the ICU.
- Do not use BRIDION to reverse nonsteroidal neuromuscular blocking agents or steroidal neuromuscular blocking agents other than rocuronium or vecuronium.
- The most common adverse reactions (reported in ≥ 10% of adult 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%). The most common adverse reactions (reported in ≥ 10% of pediatric patients 2 to <17 years of age at BRIDION doses of 2 or 4 mg/kg) were pain (65% and 61%), vomiting (14% and 13%), and nausea (10% and 11%). The most common adverse reactions (reported in ≥ 10% of pediatric patients birth to < 2 years of age at BRIDION doses of 2 or 4 mg/kg) was procedural pain (40.9% and 58%).

TOF, train-of-four; PTC, post-tetanic count; BMI, body mass index

Before administering BRIDION, please read the accompanying Prescribing Information.

For additional copies of the Prescribing Information, please call 800-672-6372, visit bridion.com, or contact your Merck representative.

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