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Press Release

Hikma launches Sugammadex Injection in a prefilled syringe in the US

London, UK, 29 July 2026 – Hikma Pharmaceuticals PLC (Hikma, Group), a multinational pharmaceutical company, today announced the launch of Sugammadex Injection in the US, at patent expiry.

“We are pleased to be among the first to bring Sugammadex Injection to patients in the US,” said Jon Kafer, Vice President of Commercial for US Injectables. "The launch of our prefilled syringes expands the options available to hospitals, pharmacists, doctors and nurses and reflects our commitment to delivering high-quality medicines in formulations that support clinical practice. This launch is another example of how Hikma is using its capabilities as a leading sterile injectable manufacturer to introduce differentiated dosage forms and serve the evolving needs of US medical professionals and their patients.”

The product has been launched in a prefilled syringe form in a 200 mg/2 mL (100 mg/mL) dose, and is indicated for the reversal of neuromuscular blockade induced by rocuronium bromide and vecuronium bromide in adult and pediatric patients aged 2 years and older undergoing surgery. Please see the full package insert for important safety information.

According to IQVIA, US sales for Sugammadex Injection were approximately $1.6 billion for the 12 months ended May 2026.

Sugammadex Injection is comparable to BRIDION® (sugammadex) injection, marketed by Merck Sharp & Dohme B.V. Hikma’s generic version is indicated for fewer than all approved indications of the Reference Listed Drug.

– ENDS –

This product has been approved for marketing in the United States by the US FDA. This product approval does not confer the right on Hikma, or any other party, to market this product outside the United States.

BRIDION® is a registered trademark of Merck Sharp & Dohme B.V.

About Hikma

Hikma helps put better health within reach every day for millions of people around the world. For more than 45 years, we've been creating high-quality medicines and making them accessible to the people who need them. Headquartered in the UK, we are a global company with a local presence across North America, the Middle East and North Africa (MENA) and Europe, and we use our unique insight and expertise to transform cutting-edge science into innovative solutions that transform people's lives. We're committed to our customers, and the people they care for, and by thinking creatively and acting practically, we provide them with a broad range of branded and non-branded generic medicines. Together, our 9,400 colleagues are helping to shape a healthier world that enriches all our communities. We are a leading licensing partner, and through our venture capital arm, are helping bring innovative health technologies to people around the world. For more information, please visit: www.hikma.com

Hikma Pharmaceuticals PLC (LSE: HIK) (NASDAQ Dubai: HIK) (OTC: HKMPY) (LEI:549300BNS685UXH4JI75) (rated BBB/stable S&P and BBB/stable Fitch)

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Important Safety Information for Sugammadex Injection

CONTRAINDICATIONS

Sugammadex injection 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.

WARNINGS & PRECAUTIONS

- **Anaphylaxis and Hypersensitivity –** Clinicians should be prepared for the possibility of drug hypersensitivity reactions (including anaphylactic reactions) and take the necessary precautions. Potentially serious hypersensitivity reactions, including anaphylaxis, have occurred in patients treated with sugammadex injection.
- **Marked Bradycardia –** Cases of marked bradycardia, some of which have resulted in cardiac arrest, have been observed within minutes after the administration of sugammadex injection.
- **Respiratory Function Monitoring During Recovery –** Ventilatory support is mandatory for patients until adequate spontaneous respiration is restored and the ability to maintain a patent airway is assured. Even if recovery from neuromuscular blockade is complete, other drugs used in the peri- and post-operative period could depress respiratory function and therefore ventilatory support might still be required.
- **Risk of Prolonged Neuromuscular Blockade –** In clinical trials, a small number of patients experienced a delayed or minimal response to the administration of sugammadex injection. Thus, it is important to monitor ventilation until recovery occurs.
- **Waiting Times for Re-Administration of Neuromuscular Blocking Agents for Intubation Following Reversal with Sugammadex Injection –** A minimum waiting time is necessary before administration of a steroidal neuromuscular blocking agent after administration of sugammadex injection. If neuromuscular blockade is required before the recommended waiting time has elapsed, use a nonsteroidal neuromuscular blocking agent.
- **Interactions Potentially Affecting the Efficacy of Other Drugs –** Due to the administration of sugammadex injection, certain drugs, including hormonal contraceptives, could become less effective due to a lowering of the (free) plasma concentrations.
- **Risk of Recurrence of Neuromuscular Blockade Due to Displacement Interactions –** Recurrence of neuromuscular blockade may occur due to displacement of rocuronium or vecuronium from sugammadex injection by other drugs. In this situation the patient may require mechanical ventilation. Administration of the drug which caused displacement should be stopped in case of an infusion.
- **Risk of Recurrence of Neuromuscular Blockade with Lower Than Recommended Dosing –** The use of lower than recommended doses of sugammadex injection may lead to an increased risk of recurrence of neuromuscular blockade after initial reversal and is not recommended.
- **Risk of Recurrence of Neuromuscular Blockade Due to the Administration of Drugs that Potentiate Neuromuscular Blockade –** When drugs which potentiate neuromuscular blockade are used in the post-operative phase, special attention should be paid to the possibility of recurrence of neuromuscular blockade. Refer to the package insert for rocuronium or vecuronium for a list of the specific drugs which potentiate neuromuscular blockade. In case recurrence of neuromuscular blockade is observed, the patient may require mechanical ventilation.
- **Risk of Coagulopathy and Bleeding –** Since bleeding risk has been studied systematically with only heparin and low molecular weight heparin thromboprophylaxis and 4 mg/kg doses of sugammadex, coagulation parameters should be carefully monitored 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.
- **Renal Impairment –** Sugammadex injection is not recommended for use in patients with severe renal impairment, including those requiring dialysis.
- **Light Anesthesia –** When neuromuscular blockade was reversed intentionally in the middle of anesthesia in clinical trials, e.g., when investigating urgent reversal, signs of light anesthesia were noted occasionally.
- **Reversal after Rocuronium or Vecuronium Administration in the ICU –** Sugammadex injection has not been studied for reversal following rocuronium or vecuronium administration in the ICU.
- **Reversal of Neuromuscular Blocking Agents Other Than Rocuronium or Vecuronium –** Do not use sugammadex injection to reverse blockade induced by nonsteroidal neuromuscular blocking agents such as succinylcholine or benzylisoquinolinium compounds. Do not use sugammadex injection to reverse neuromuscular blockade induced by steroidal neuromuscular blocking agents other than rocuronium or vecuronium.

ADVERSE REACTIONS

- Most common adverse reactions (reported in ≥10% of adult patients at a 2, 4, or 16 mg/kg sugammadex injection dose and higher than the placebo rate): vomiting, pain, nausea, hypotension, and headache.
- Most common adverse reactions (reported in ≥10% of pediatric patients 2 to <17 years of age at sugammadex injection doses of 2 or 4 mg/kg): pain, vomiting, and nausea.

DRUG INTERACTIONS

Interactions Potentially Affecting the Efficacy of Sugammadex Injection

For toremifene, which has a relatively high binding affinity for sugammadex and for which relatively high plasma concentrations might be present, some displacement of vecuronium or rocuronium from the complex with sugammadex injection could occur. The recovery to TOF ratio to 0.9 could therefore be delayed in patients who have received toremifene on the same day of surgery.

Interaction Potentially Affecting the Efficacy of Hormonal Contraceptives

In vitro binding studies indicate that sugammadex injection may bind to progestogen, thereby decreasing progestogen exposure. Therefore, the administration of a bolus dose of sugammadex injection is considered to be equivalent to missing dose(s) of oral contraceptives containing an estrogen or progestogen. If an oral contraceptive is taken on the same day that sugammadex injection 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.

Interference with Laboratory Tests

Sugammadex injection may interfere with the serum progesterone assay. Interference with this test was observed at sugammadex plasma concentrations of 100 mcg/mL, which may be observed for up to 30 minutes after a 16 mg/kg dose.

USE IN SPECIFIC POPULATIONS

Geriatric Use

This drug is known to be substantially excreted by the kidney, and the risk of adverse reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

Hepatic Impairment

Exercise caution when administering sugammadex injection to patients with hepatic impairment accompanied by coagulopathy or severe edema.

OVERDOSAGE

In premarketing clinical trials, one case of accidental overdose with 40 mg/kg sugammadex injection was reported without significant effects. Sugammadex injection can be removed using hemodialysis with a high-flux filter, but not with a low-flux filter. Based upon clinical studies, sugammadex injection concentrations in plasma are reduced with a high-flux filter by about 70% after a 3- to 6-hour dialysis session.

INDICATIONS AND USAGE

Sugammadex injection is indicated for the reversal of neuromuscular blockade induced by rocuronium bromide and vecuronium bromide in adult and pediatric patients aged 2 years and older undergoing surgery.

Additional pediatric use information is approved for Merck Sharp & Dohme LLC's BRIDION® (sugammadex) injection. However, due to Merck Sharp & Dohme LLC's marketing exclusivity rights, this drug product is not labeled with that information.

ENDING INFORMATION

Patient Counseling Information should be shared with the patient prior to administration.
For additional information, please refer to the Package Insert for full prescribing information, available on www.hikma.com.

To report SUSPECTED ADVERSE REACTIONS, contact Hikma Pharmaceuticals USA Inc. at 1-877-845-0689 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Manufactured by:
Hikma Pharmaceuticals USA Inc.
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BRIDION is a registered trademark of Merck Sharp & Dohme B.V.