Sugammadex Sodium

【IBRID】Bridion® 100mg/mL, 2mL/vial *ATC Code：V03AB35*

中文名： 倍帝恩注射液 «莫沙東»

適應症： 用於成人、2 歲以上兒童及青少年因 rocuronium 或 vecuronium 誘導神經肌肉阻斷的逆轉藥物。

藥理分類： Antidote; Selective Relaxant Binding Agent.

用法用量： **Administration:**

Adult:

- **IV**: Administer as rapid IV push over 10 seconds (according to the manufacturer).
- If administered in same IV line as other products, **flush with saline before and after** administration of sugammadex.
- some experts suggest administering slow IV push to reduce incidence of serious adverse events (eg, bradycardia or asystole).

Pediatric:

- **Infants and Children <2 years:**
  - ✧ Dilution was administered over 10 seconds;
  - ✧ some experts suggest administering slow IV push to reduce the incidence of serious adverse events (eg, bradycardia, asystole).
- **Children ≥2 years and Adolescents**:
  - ✧ Administer diluted (10 mg/mL) or undiluted (100 mg/mL) over 10 seconds;
  - ✧ some experts suggest administering slow IV push to reduce the incidence of serious adverse events (eg, bradycardia, asystole).

Indications and dosage regimen:

Note: Dosing based on **actual body weight**.

Routine reversal of rocuronium- or vecuronium-induced blockade:

- **Deep block (at least 1 to 2 post-tetanic counts and prior to the second twitch following train-of-four [TOF] stimulation):** 4 mg/kg as a single dos.
- **Moderate block (after appearance of the second twitch following TOF stimulation):** 2 mg/kg as a single dose.
- **Readministration of rocuronium or vecuronium:** Following sugammadex use for routine reversal, waiting times for readministration of rocuronium or vecuronium vary greatly (5 minutes to 24 hours) depending on agent, dose, and renal function (consult product labeling); if immediate neuromuscular blockade is needed, a nonsteroidal neuromuscular-blocking agent (eg, cisatracurium or atracurium) may be required.

Immediate reversal of rocuronium-induced blockade:

- **16 mg/kg** as a single dose administered soon (~3 minutes) after administration of a single dose of rocuronium 1.2 mg/kg.
- Note: This dose of sugammadex has not been evaluated following administration of vecuronium.
- **Readministration of rocuronium or administration of vecuronium:** Following sugammadex use for immediate reversal of rocuronium, wait 24 hours before readministering rocuronium or administering vecuronium. If more immediate neuromuscular blockade is needed, a nonsteroidal neuromuscular-blocking agent (eg, cisatracurium or atracurium) may be required.

Dosing: Kidney Impairment: Adult

- CrCl 30 to 80 mL/minute: No dosage adjustment necessary.
- CrCl < 30 mL/minute: Use is not recommended.
- Dialysis: Use is not recommended.

Dosing: Obesity: Adult

- **2 or 4 mg/kg** (based on moderate or deep level of block) using **actual body weight.**

不良反應： 味覺障礙，頭痛，噁心，蕁麻疹，瘙癢，暈眩，嘔吐和腹痛。

注意事項：

- 單次靜脈注射 sugammadex 時應儘速完成，在 10 秒鐘內注入現存的靜脈注射管線中。
- 對已知患有凝血疾病的病人及正在使用抗凝血劑的病人，如果使用 16 mg/kg 之劑量的 sugammadex，應依常規的臨床實務密切監測凝血參數。
- 不建議對重度腎功能不全病人施用 sugammadex，包括那些需要洗腎的病人。

懷 孕 期： 目前並無相關的安全資料。對孕婦施用 sugammadex 時應特別謹慎。

授 乳 期： 無法得知 sugammadex 是否會分泌到人類乳汁中，但動物研究結果顯示 sugammadex 會分泌到乳汁中。對餵哺母乳的婦女投予 sugammadex 時應謹慎。

配 製：

- **成人：**不稀釋，直接使用。
- **兒童和青少年（2 歲及以上）**：以 NS 將 100mg/mL 的 Bridion 稀釋至 10 mg /mL，以提高小兒族群給藥的正確性。
  - ✧ 將含有 200 mg sugammadex (100 mg/mL)的 Bridion2-mL 單劑量小瓶的 2 mL 小瓶中的所有內容物，無菌轉移到含有 18 mL NS 注射液的瓶子（或靜脈輸液袋）中，以達到 10 mg/mL sugammadex 的最終濃度。

安 定 性：

- 首次開啟及稀釋後在 5-25℃下的**化學及物理穩定性**可達 48 小時。
- **從微生物觀點**來看，稀釋後的產品應立即使用。如果未立即使用的話，而且通常在 5-8℃下不應超過 24 小時。
- Bridion 注射液是一種不含防腐劑的單劑量無菌溶液。未使用的部分應丟棄。

相容輸注液： NS

儲 存： 儲存於 30℃以下。切勿冷凍。避免光線直射。在未避光存放的情況下，本品應於 5 天內使用。