Medicines & Healthcare products Regulatory Agency

MEDICINES NOTIFICATION

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use
Pharmacy/Wholesaler Level

Date: 18 January 2024 EL (24)A/02 Our Ref: MDR 271-10/23

Dear Healthcare Professional,

USV UK Limited

Sugammadex 100 mg/ml solution for injection (2 ml vial) PL 32870/0059

SNOMED Code: N/A

Batch No	Expiry Date	Pack Size	First Distributed
35000347	05-2025	1 x 10	22 August 2023

Active Pharmaceutical Ingredient: Sugammadex Sodium

Brief description of the problem
USV UK Limited has informed the MHRA that Sugammadex 100 mg/ml solution for injection (2 ml vial), batch number 35000347, may contain some vials that contain a low volume of solution; less than the label claim of 2 ml. USV UK Limited has received a single market complaint of a vial containing 1.6 ml of product, which has been confirmed with additional testing. This notification is a precautionary measure to inform healthcare professionals of the potential for some vials in the specific batch listed in this notification to be of lower volume. Due to considerations related to product supply, this batch is not being recalled.

Advice for healthcare professionals
Healthcare professionals are advised to check stock levels of Sugammadex 100 mg/ml solution for injection (2 ml vials) with batch number 35000347 and consider that additional vials may need to be used to supplement the required dosage in line with the requirement of individual patient treatment.

Healthcare professionals are reminded of the information in Section 4.2 Posology and method of administration in the Summary of Product Characteristics (SmPC): Click here for link to SmPC

Advice for patients
Patients do not need to take any action. This product is given to patients by trained healthcare professionals. This notification is to provide healthcare providers with information that some vials may contain less than the labelled volume. There is no impact to patient safety, efficacy or product quality. Healthcare professionals will ensure that the appropriate dose is provided.

Patients who experience adverse reactions or have any questions about the medication should seek medical attention. Any suspected adverse reactions should also be reported via the MHRA Yellow Card scheme.

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Further information
For medical information enquiries please contact medical info at USV on medicalinfo@usvuk.com or phone: 00 800 89013370

For stock control enquiries please contact Novumgen on tapan.parmar@novumgen.uk or phone: 0203 096 6496 on extension 5 (Please note Novumgen is the first-line distributor of USV UK products in the UK).

Recipients of this Medicines Recall should bring it to the attention of relevant contacts by copy of this notice. NHS regional teams are asked to forward this to community pharmacists and dispensing general practitioners for information.

Yours faithfully

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