



MEDICINES RECALL

CLASS 2 MEDICINES RECALL

Action Within 48 Hours
Pharmacy/Wholesaler Level Recall

Date: 28 April 2022

EL (22)A/20

Our Ref: MDR 176-04/22

Dear Healthcare Professional,

Fresenius Kabi Limited

Sodium bicarbonate 1.26% Solution for infusion

PL 08828/0013

Batch Number	Expiry Date	Pack Size	First Distributed
22BC01	02/2023	500ml	31 st March 2022

Active Pharmaceutical Ingredient: sodium bicarbonate

Brief description of the problem

Fresenius Kabi Limited are recalling the above batch of product as a precautionary measure due to the identification of particles in the solution for infusion, following routine batch analysis and subsequent batches manufactured on the same filling line. The company's investigation indicates that the particles appear to originate from the interaction between the equipment and the packaging material during the filling process. The integrity of the packaging and sterility of the product are not compromised.

Advice for healthcare professionals

Stop supplying the above batch immediately. Quarantine all remaining stock and return it to your supplier using your supplier's approved process. Healthcare professionals are advised to monitor patients where appropriate and report suspected adverse events to the company or via the [MHRA Yellow Card scheme](#).

Advice for patients

- This is a precautionary Pharmacy and Wholesaler level recall, therefore no further action is required by patients. This product is normally administered by healthcare professionals in a hospital setting.
- The Marketing Authorisation Holder have not received any reports of adverse reactions related to the issue above, however, patients who experience any adverse reactions should seek medical attention. These should also be reported via the [MHRA Yellow Card scheme](#).

Further Information

For more information, medical or supply enquiries, please contact 01928 533 758 [FK.Complaints-UK@fresenius-Kabi.com](#) or [Customer.Services-UK@Fresenius-Kabi.com](#)

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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