Department of Health
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For Action: Assistant Director Integrated Care, Head of Pharmacy and Medicines Management, Strategic Planning and Performance Group & BSO
Heads of Pharmacy and Medicines Management of HSC Trusts
Regulation Quality Improvement Authority

From: Chief Pharmaceutical Officer
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Our Ref: PHC/10/2024
Date: 21 March 2024

MEDICINES NOTIFICATION

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use
Pharmacy/Wholesaler Level

Dear Healthcare Professional,

Fresenius Kabi Limited

Sodium Chloride Intravenous Infusion 0.9% Freeflex **PL 08828/0084**

SNOMED Code: 40545111000001108

Batch No	Expiry Date	Pack Size	First Distributed
13SMR091	30/11/2025	50 x 100 ml	19/02/2024
13SMR061	30/11/2025	50 x 100 ml	Not Yet Distributed
13TAR011	31/12/2025	50 x 100 ml	Not Yet Distributed
13SLR271	31/10/2025	50 x 100 ml	Not Yet Distributed

Active Pharmaceutical Ingredient: Sodium Chloride for Injections 0.9% w/v

Brief description of the problem

Fresenius Kabi Limited has informed the MHRA of an error on the infusion bag packaged into the specific batches of Sodium Chloride Intravenous Infusion 0.9% Freeflex mentioned in this notification. The error has been identified in the contents box (active substance section). It is incorrectly printed ‘Each 50 ml contains approx’; this should state ‘Each 100 ml contains approx’.

The correct quantity is stated on the outer carton and in the Summary of Product Characteristics.

Advice for healthcare professionals

The quality of the product is not impacted by this labelling error; therefore the affected batches are not being recalled. Healthcare professionals are advised to exercise caution when administering this product, particularly when performing electrolyte or dilution calculations.

The manufacturer has confirmed that the batches that have yet to be distributed will be accompanied by a note explaining the issue. These batches will not be repackaged to avoid any supply concerns.

Fresenius Kabi Limited has confirmed that all production of future batches will contain an infusion bag with the correct declaration of the amount of electrolytes.

Advice for patients

No action is needed from patients. Patients should continue to receive this medicine from these batches as given to you by your healthcare professional. There is no impact to product quality. 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.

Further Information

For more information or medical information queries please email Medical.Information-UK@fresenius-kabi.com or telephone +44 (0)1928533575

For stock control enquiries please contact FK.complaints-uk@fresenius-kabi.com or telephone +44 (0) 1928 533758

Recipients of this Medicines Recall should bring it to the attention of relevant contacts by copy of this notice. RQIA should bring this information to the attention of private hospitals/clinics registered with them and any other relevant care facilities.

The Business Services Organisation is asked to bring this information to the attention of Community Pharmacists and General Medical Practitioners directly.

Yours sincerely

Professor Cathy Harrison
Chief Pharmaceutical Officer