Medicines & Healthcare products Regulatory Agency

# MEDICINES NOTIFICATION

## CLASS 4 MEDICINES DEFECT INFORMATION

**Caution in Use**
**Pharmacy/Wholesaler Level**

Date: 21 March 2024 EL (24)A/10 Our Ref: MDR 332-02/24

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.

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**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. NHS regional teams are asked to forward this to community pharmacists and dispensing general practitioners for information.

Yours faithfully

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