Medicines & Healthcare products Regulatory Agency

M E D I C I N E S N O T I F I C A T I O N

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use
Distribute to Pharmacy / Wholesaler Level

Date: 24 July 2024 EL (24)A/31 Our Ref: 31178038

Dear Healthcare Professional,

Fresenius Kabi Limited

Hartmann's Solution for Injection BP as Steriflex No. 11 or freeflex PL 08828/0083

SNOMED Code 4900111000001102

Batch Number	Expiry Date	Pack Size	First Distributed
14TB7322	18/02/2027	20 x 500 ml	13/04/2024
14TD7312	02/04/2027	20 x 500 ml	09/07/2024
14TE7326	20/05/2027	20 x 500 ml	Not yet distributed

Active Pharmaceutical Ingredient: sodium chloride, potassium chloride, calcium chloride dihydrate, sodium lactate

Brief description of the problem
Fresenius Kabi Limited has informed the MHRA of a labelling error on the packaging of Hartmann's solution for Injection BP as Steriflex No.11 or freeflex. The calcium content in the active ingredient section of the infusion bag label is incorrectly stated as '12 mmol/500 mL'; this should state '1 mmol/500 mL'.

The calcium content is stated correctly on the outer carton, and the infusion bags contain the correct amount of calcium (1 mmol/500 mL).

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 supplying and when administering the product.

Fresenius Kabi Limited has confirmed that all production of future batches will contain the correct calcium content stated on the infusion bag. However, batch 14TE7326, which has yet to be distributed, will not be repackaged to avoid any supply concerns.

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 Notification 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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