Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

DRUG ALERT

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use
Distribute to Pharmacy Level

Date: 13 August 2020 EL (20)A/39 Our Ref: MDR 062-08/20

Dear Healthcare Professional,

Fresenius Kabi Ltd & Calea UK Ltd

SmofKabiven extra Nitrogen Electrolyte Free PL 08828/0269

Product Code	Batch Number	Expiry Date	Bag Size	First Distributed
833004220	10NI3300	31 Aug 2021	1518ml	05 May 2020
833012220	10PB8836	31 Jan 2022	2025ml	10 Aug 2020

Brief description of the problem
Fresenius Kabi Ltd & Calea UK Ltd has informed us of an error on the bag labels for SmofKabiven extra nitrogen electrolyte free, emulsion for infusion PL 08828/0269. A sentence has been inadvertently included stating “with electrolytes” on an electrolyte free product. The outer cartons and leaflets have been checked and these are all in compliance. The bag label should state “1. Amino acid solution”.

Advice for healthcare professionals

This alert is for information only. There are no concerns with the product quality, safety or efficacy and therefore the product is not being recalled. Healthcare professionals should be aware that there is a product available with electrolytes and caution should be exercised when dispensing and administering this product.

Further Information
For more information or medical information queries, please contact:
Medical.Information-UK@fresenius-kabi.com

Recipients of this Drug Alert 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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