

MEDICINES NOTIFICATION

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use
Distribute to Pharmacy/Wholesaler Level

Dear Healthcare Professional

Fresenius Kabi Limited

SmofKabiven Central emulsion for Infusion

PL 08828/0187

Batch No	Expiry Date	Pack Size	First Distributed
10PK7682	30 Sep 2022	4 x 986 ml 3-chamber infusion bag	01 Dec 2020
10PL9065	31 Oct 2022	4 x 986 ml 3-chamber infusion bag	22 Dec 2020
10QA9950	31 Dec 2022	4 x 986 ml 3-chamber infusion bag	22 Feb 2021
10QC4068	28 Feb 2023	4 x 986 ml 3-chamber infusion bag	21 May 2021
10QG7923	30 Jun 2023	4 x 986 ml 3-chamber infusion bag	28 Aug 2021
10QI9859	31 Aug 2023	4 x 986 ml 3-chamber infusion bag	19 Oct 2021
10QL2802	31 Oct 2023	4 x 986 ml 3-chamber infusion bag	Not distributed yet

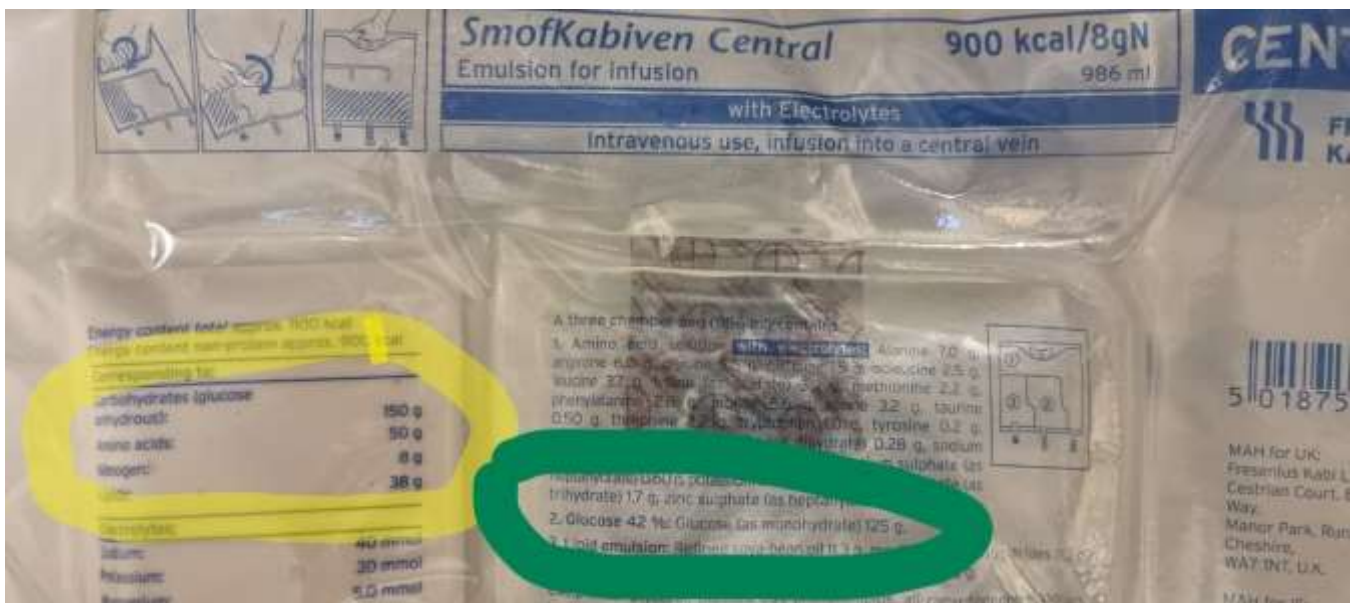
Active Pharmaceutical Ingredients: Alanine, arginine, glycine, histidine, isoleucine, leucine, lysine (as acetate), methionine, phenylalanine, proline, serine, taurine, threonine, tryptophan, tyrosine, valine, calcium chloride (as dihydrate), sodium glycerophosphate (as hydrate), magnesium sulphate (as heptahydrate) potassium chloride, sodium acetate (as trihydrate), zinc sulphate (as heptahydrate), glucose (as monohydrate), soya-bean oil; refined, medium-chain triglycerides, olive oil; refined and fish oil; rich in omega-3-acids.

Brief description of the problem

Fresenius Kabi Limited have identified an error on the infusion bag packaged into the above batches. In the energy content section printed onto the bag the amount of carbohydrates (glucose anhydrous) has been incorrectly declared as 150 g, the actual amount is 125 g.

The correct amount of carbohydrates (as monohydrate) is correctly declared on the infusion bag under the ingredients section as **glucose 42%**: glucose (as monohydrate) 125 g. The correct amount is also stated on the outer carton and in the SmPC.

The photograph below is of an infusion bag with the error, the yellow circle indicates the location where the carbohydrates (glucose anhydrous) are incorrectly declared and the green circle highlights where the glucose content is correctly declared.



Advice for healthcare professionals

There is no risk to product quality as a result of this issue, therefore the affected batches are not being recalled. Healthcare professionals are advised to exercise caution when administering this product particularly when calculating patient nutritional requirements.

Fresenius Kabi Limited have confirmed that all future batches will contain an infusion bag with the correct declaration of carbohydrates (glucose anhydrous).

Further Information

For more information or medical information queries please contact:

Medical.Information-UK@fresenius-kabi.com

Recipients of this Medicines Notification should bring it to the attention of relevant contacts by copy of this notice

Recipients of this Medicines Recall should bring it to the attention of relevant contacts by copy of this notice.

TO ALL CHEMISTS, DOCTORS ON THE LISTS

Pharmaceutical Services
2 Franklin Street
BELFAST
BT2 8DQ

Telephone No. 028 9536 0333

16th December 2021