



MEDICINES NOTIFICATION

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use
Distribute to Pharmacy/Wholesaler Level

Date: 25 January 2022

EL (22)A/02

Our Ref: MDR 117-01/22

Dear Healthcare Professional,

Fresenius Kabi Limited

Kabiven Emulsion for Infusion

PL 08828/0131

Batch No	Expiry Date	Pack Size	First Distributed
10PC9374	28 Feb 2022	4 x 2053 ml 3-chamber infusion bag	05 May 2020
10PE3357	30 Apr 2022	4 x 2053 ml 3-chamber infusion bag	22 Sep 2020
10PM9641	30 Nov 2022	4 x 2053 ml 3-chamber infusion bag	20 Apr 2021
10QA1922	31 Dec 2022	4 x 2053 ml 3-chamber infusion bag	23 Apr 2021
10QD5451	31 Mar 2023	4 x 2053 ml 3-chamber infusion bag	04 Oct 2021
10QH8524	31 Jul 2023	4 x 2053 ml 3-chamber infusion bag	06 Jan 2021

Active Pharmaceutical Ingredients: Purified soyabean oil, glucose monohydrate, alanine, arginine, aspartic acid, glutamic acid, glycine, histidine, isoleucine, leucine, lysine hydrochloride, methionine, phenylalanine, proline, serine, taurine, threonine, tryptophan, tyrosine, valine, calcium chloride (as dihydrate), sodium glycerophosphate (as hydrated), magnesium sulphate (as heptahydrate) potassium chloride, sodium acetate (as trihydrate).

Brief description of the problem

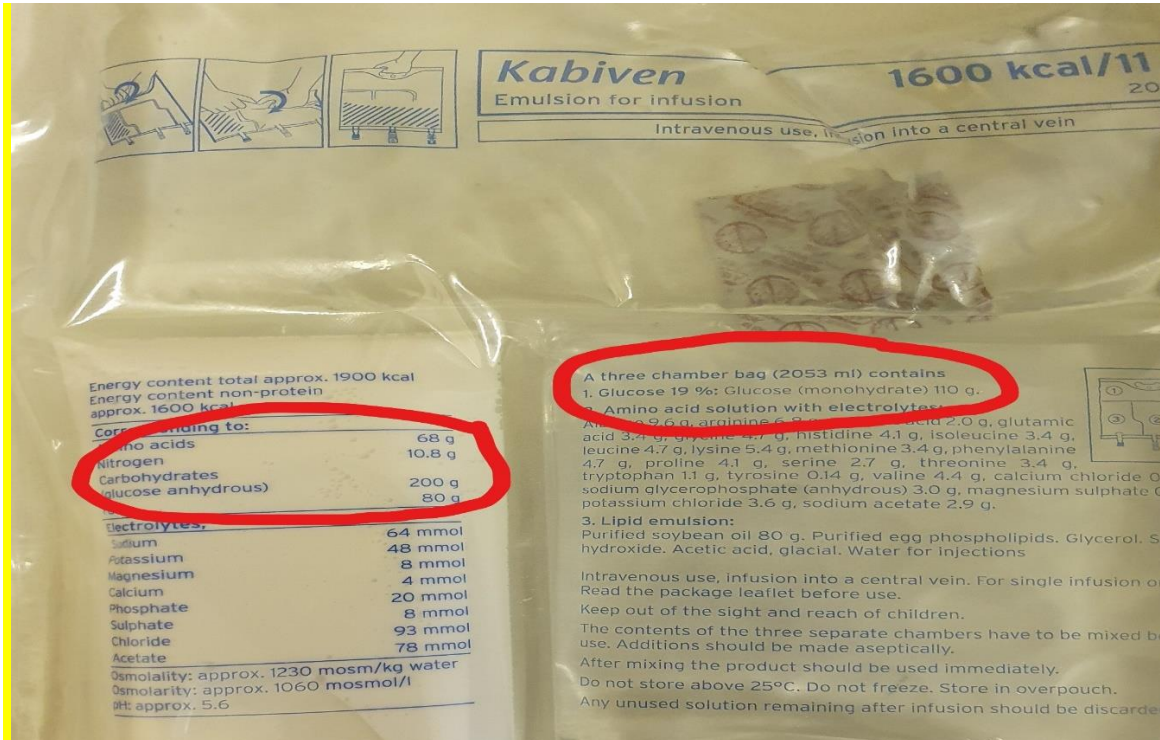
Fresenius Kabi Limited have identified an error in the infusion the infusion bag packaged into the above batches. In the list of ingredients section printed onto the bag, the amount of **Glucose 19 %: Glucose (monohydrate)** has been incorrectly declared as 110 g, the actual amount is 220 g.

The correct amount of carbohydrates (as glucose anhydrous) is correctly declared on the infusion bag within the energy content section as 200 g. The correct amounts are also stated on the outer carton and in the SmPC.

All other Kabiven bag sizes state the correct amount of glucose in both monohydrate and anhydrous form.



The photograph below is of an infusion bag with the error, on the left-hand side of the photograph circled in red in the correctly declared amount of glucose anhydrous, 200 g, and on the right-hand side of the photograph also circled in red is the incorrectly declared amount of glucose monohydrate, 110 g.



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 the amount of glucose monohydrate and equivalent 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. NHS regional teams are asked to forward this to community pharmacists and dispensing general practitioners for information.

Yours faithfully

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