

DRUG ALERT

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use

Distribute to Pharmacy/Wholesaler Level

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).

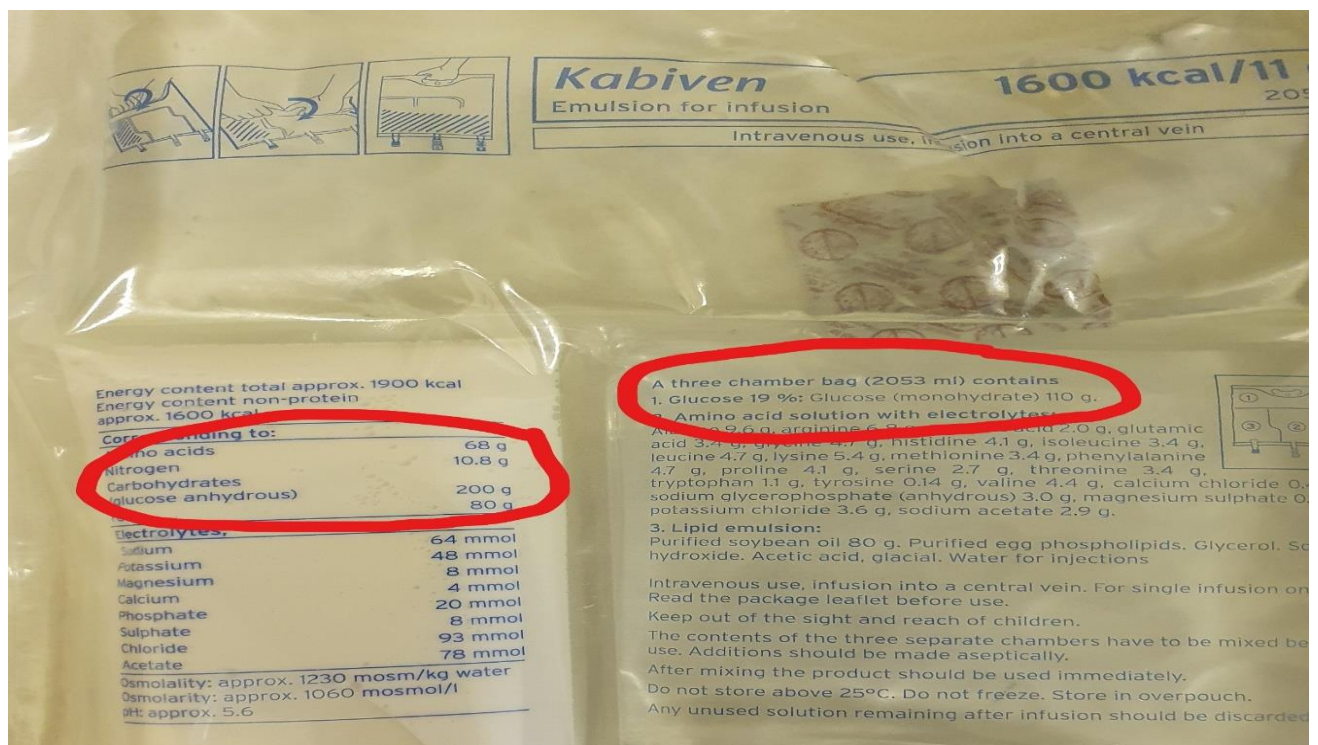
Brief description of the problem

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

RQIA should bring this information to the attention of private hospitals/clinics registered with them and any other relevant care facilities

The Business Services Organisation is asked to bring this information to the attention of Community Pharmacists and General Medical Practitioners directly.

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TO ALL CHEMISTS, DOCTORS ON THE LISTS

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25th January 2022

Pharmaceutical website: <http://www.hscbusiness.hscni.net>