



Date: 18/05/2021

URGENT SAFETY INFORMATION

Recall Potassium additive solution for haemodialysis concentrates 54 ml Article FE1010067, batch number L201714

Dear customer,

Laboratorium Dr. G. Bichsel AG has received notification of a quality deviation in the above product. An overfilled bottle was detected.

Affected product references (table 1)

Article	Product name	Batch number	Expiration date
FE1010067	Potassium additive solution for haemodialysis concentrates 54 ml = 189 mmol K+, PPF with 54 ml each	L201714	30/09/2023

To ensure patient safety, it was decided to recall the affected batch from the market as a precautionary measure.

There are no reports of adverse effects in patients.

Problem description

A customer has noticed a clear deviation in the filling quantity, within the meaning of overfilling, in a bottle of the above batch (L201714). According to current knowledge, this is an isolated incident.

Implications for patients and users

Due to the above, there is a potential risk of potassium overdose during haemodialysis, which could result in mild to severe hyperkalaemia in the patient.

Corrective action

Laboratorium Dr. G. Bichsel AG informs all supplied customers as a corrective measure to order the blocking and recall of the still existing goods of the affected batch with immediate effect.

All returned units are subjected to a further control.

Laboratorium Dr. G. Bichsel AG has not yet received any reports of adverse events that could be related to this corrective measure. If the product has already been used, no additional specific measures are required for patient follow-up.



Laboratorium Dr. G. Bichsel AG

Fabrikation steriler Lösungen · Versorgungszentrum für Heimpatienten

Weissenastrasse 73, CH-3800 Interlaken, Tel. +41 (0)33 827 80 00, Fax +41 (0)33 827 80 99, info@bichsel.ch, www.bichsel.ch

Required measures at the customer's, procedure to comply with this recall:

1. Check your stock and quarantine the affected batch according to table 1.
2. Do not use the bottles of batch L201714 anymore.
3. Using the reply form, inform Laboratorium Dr. G. Bichsel AG of the quantity of bottles of the affected batch of medical devices in stock and return them. You will receive a credit note for the returned goods.

All products with a different batch number than the one affected by the recall can be used without any problems.

We request that you return the completed response form as soon as possible, but no later than 28/05/2021 via email to pharmacovigilance@bichsel.ch.

We thank you for your cooperation, apologise for any inconvenience caused and will be happy to answer any further questions you may have on +41 33 827 82 18.

Kind regards,

A handwritten signature in blue ink, appearing to read "Dr. Tamara Bauer".

Dr. Tamara Bauer
Head of QM, PRs



Laboratorium Dr. G. Bichsel AG

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Reply form

Recall Potassium additive solution for haemodialysis concentrates 54 ml
Article FE1010067, batch number L201714

Please read in conjunction with the recall letter regarding Urgent Safety Information dated May 18th 2021.

Please send this form back to pharmacovigilance@bichsel.ch.

Name of the company:	
Address:	
Name of the contact person:	
Email:	

- ☐ We confirm that we have received, read and understood the note on the Urgent Safety Information.
- ☐ We hereby declare that, with immediate effect, we will no longer use the batch listed in the safety information and will return the goods still in stock (according to the information on "Quantity" in table 2). We are requesting a corresponding credit note for goods.

Credit note for returned goods (table 2):

Article	Product name	Batch number	Expiration date	Quantity (please fill in)
FE1010067	Potassium additive solution for haemodialysis concentrates, 54 ml = 189 mmol K+, PPF with 54 ml each	L201714	30/09/2023	

Date, signature and stamp:
