

**IMPORTANT
SAFETY
INFORMATION**

22ND JULY, 2008

**Subject : ACCUSOL 35 solution for Haemofiltration, Haemodialysis and Haemodiafiltration
Precipitate formation during Continuous Renal Replacement Therapy (CRRT)**

Dear Healthcare Professional:

Baxter Healthcare is sending this letter to provide you with important product safety information regarding ACCUSOL 35, solution for Haemofiltration, Haemodialysis and Haemodiafiltration packaged in 5 liter Clearflex bags (registered as a drug).

It is important to note that this information is limited to Accusol 35, solution for Haemofiltration, Haemodialysis and Haemodiafiltration indicated for use as substitution solution and registered as a drug through MRP n°UK/H/0813/001 (PL00116/0414), UK/H/0839/001 (PL 00116/0415) and UK/H/0839/002 (PL 00116/0416).

The products registered as a drug are the following:

- Product Codes: Accusol 35 – FPE9003, BWPE9003C
Accusol 35 with 2 mmol/l potassium – FPE9004, BWPE9004C
Accusol 35 with 4 mmol/l potassium – FPE9005, BWPE9005C

This safety information does not impact Accusol Dialysis Solution, which is registered as a medical device, (CE marked), intended to be used during Continuous Renal Replacement Therapy (CRRT) for acute renal failure, where the Accusol solution serves as dialysate solution, is not to be used as a substitution solution, and is not for direct intravenous infusion.

The medical device products not impacted by this safety information are the following:

- Accusol K+0, K+2 and K+4 registered in Clearflex 5L - Product codes: SPE9245, SPE9246 and SPE9247
- Accusol K+0, K+2 and K+4 registered in PVC 2,5L - Product codes: SPM4181, SPM4182 and SPM4183

Background

Baxter Healthcare has recently received an increased number of reports of visible white precipitate forming during haemofiltration in Continuous Renal Replacement Therapy (CRRT) lines while using Accusol 35. The total number of reports received as of 17 July is 42. The majority of these reports have been received in May and June 2008 from the UK, but reports have also been received from Poland and Australia. If present, precipitate is typically observed in either the pre-dilution or post-dilution lines after several hours of therapy.

Precautions

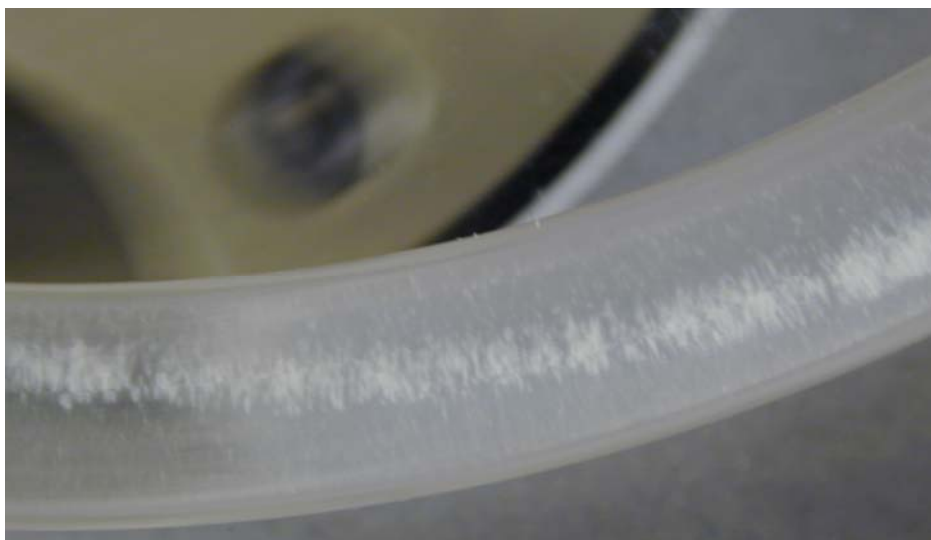
Due to the potential safety risk associated with precipitate formation it is important to take caution. **Baxter Healthcare advises that pre-dilution and post-dilution lines are inspected at the start of the therapy and thereafter every 30 minutes during CRRT with Accusol 35 solutions. In the event precipitate is observed, the CRRT session should be stopped and the blood returned to the patient using normal saline. If the patient requires further CRRT treatment, a new tubing set, haemofilter/dialyzer, and ACCUSOL solution should be used before continuing.**

Alternatively, CRRT can be continued using haemodialysis.



Baxter Healthcare is conducting a thorough investigation to determine the root cause of the precipitate. Based on this analysis Baxter will take the appropriate corrective action to ensure that the underlying source of the precipitate is properly addressed. While the root cause investigation is in progress, the precipitate has been identified as calcium carbonate.

If any precipitate formation is observed (see an example below) or any adverse reaction is suspected during the use of Accusol 35, please report this to Baxter Healthcare at Tel: 01635 206345.



Example of white precipitates that might be observed in either the pre-dilution or post-dilution lines.

If you provide this product to other services or facilities, please forward this information as appropriate.

The Medicines and Healthcare products Regulatory Agency has been notified of this action.

We apologize for any inconvenience you and your staff may experience as a result of this notification.

If you have any questions, please contact Miss Andleeb Arshad, at Edwards Lifesciences Ltd, Direct Tel: 01635 27 7302.

Sincerely,

A handwritten signature in black ink that reads "C. Holton".

Catherine Holton
Haemotherapies Product Manager
Renal Division
Baxter Healthcare Limited