



From The Chief Pharmaceutical Officer
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For Action: Directors of Pharmaceutical Services of the Boards & CSA
Directors of Pharmaceutical Services of HSC Trusts
Regional Quality Improvement Authority

Our reference: PHC/10/08

Date: 23 July 2008

DRUG ALERT

(Caution in use)

Dear Healthcare Professional

Baxter Healthcare Ltd

Accusol 35 Solution	PL 00116/0414
Accusol 35 Potassium 2 mmol/l	PL 00116/0415
Accusol 35 Potassium 4 mmol/l	PL 00116/0416

The MHRA has been informed that some batches of the above Accusol 35 products have formed visible white precipitate during haemofiltration in Continuous Renal Replacement Therapy (CRRT). The precipitate has been identified as Calcium Carbonate and has normally been seen in either the pre-dilution or post-dilution lines after several hours of therapy.

The root cause of this problem remains under investigation and we understand that Baxter Healthcare cannot yet establish a date when fully acceptable replacement stock will become available. **Until more information becomes available we advise in-use inspection of all batches of Accusol 35 licensed solutions as detailed below.**

We understand that alternative products, from other manufacturers, are not available in sufficient amounts to recommend recall of Accusol 35 products and replacement with alternative therapies.

Advice for Accusol 35 Use in CRRT Therapy

Baxter Healthcare advise that pre-dilution and post-dilution lines are inspected at the start of therapy and thereafter at least every 30 minutes during CRRT with Accusol 35 solutions. If 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 then a new tubing set, haemofilter/dialyzer and Accusol 35 solution should be used before continuing Alternatively, CRRT can be continued using haemodialysis.

If any precipitate formation is observed or any adverse reaction is suspected during the use of Accusol 35, please report by telephone to Baxter Healthcare on 01635 206345.

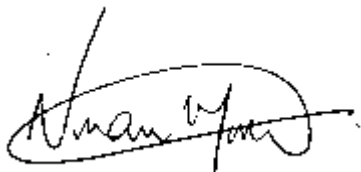
Further information

For medical enquiries, please telephone Baxter Healthcare Medical Information on 01635 206345. This advice applies to the above licensed presentations only. Baxter Healthcare Ltd also market Accusol Dialysis Solution which is registered as a medical device. Accusol Dialysis Solution is not affected and is not included in the scope of this notice.

Directors of Pharmacy of Trusts should bring this information to the attention of Renal Units and Intensive Care Units by copy of this letter.

Area Boards/RQIA should bring this information to the attention of private hospitals/clinics registered with them, Out of Hours Centres and any other relevant care facilities.

Yours sincerely



DR NORMAN MORROW
Chief Pharmaceutical Officer

For information:
CMO
CNO
CDO
CISSI
SMO
Director, Health Estates
Public Health Branch
DHSSPS, Library
Extended nurse prescribers

Regional Medicines and Poisons Information Service
Regional Director of Supplies
RPLS
Pharmaceutical Society of NI
Senior Prison Pharmacist
Prison Service, Dundonald House
Nursing Officer, Health Estates
Medical Officer, Castle Buildings
Regional Procurement Pharmacist
NICPPET