

January 2012

Direct Healthcare Professional Communication on the resumed distribution of Monosol solution

Dear Healthcare Professional,

Monosol is a haemodialysis, haemodiafiltration and haemofiltration solution manufactured by Baxter Healthcare.

In January 2011, all Monosol batches were recalled from the market because of a manufacturing problem at the Baxter site in Castlebar, Ireland. Monosol was produced using a specific manufacturing line on which some batches of peritoneal dialysis (PD) solutions were found to have elevated levels of endotoxin. All batches of those PD solutions were recalled. While no adverse events were reported specifically with Monosol related to endotoxin, all batches of Monosol were also recalled as a precautionary measure.

We are now writing to inform you that the manufacture and distribution of Monosol solution will resume at the end of January 2012 following a variety of corrective and preventative measures.

Further information

Healthcare professionals were informed in December 2010 and January 2011 of the potential endotoxin issue at the Castlebar site.

In October 2011 the European Medicines Agency (EMA) and its Committee for Medicinal Products for Human Use (CHMP) finalised recommendations for quality improvement measures at the Castlebar manufacturing plant to ensure the continued supply of endotoxin-free PD and Monosol solutions. The conclusion of the EMA/CHMP was that healthcare professionals and patients can now be reassured that a variety of corrective and preventative measures have now taken place to ensure the quality of Baxter's products from the manufacturing lines concerned, including Monosol.

Call for Adverse Event Reporting

If you observe any suspected adverse events (AEs) in association with Monosol, please report the adverse event to Baxter UK Pharmacovigilance at Baxter Healthcare Ltd, Wallingford Road, Compton, Newbury RG20 7QW,
by email to vigilanceuk@baxter.com,
by fax to 01635 206281
or report by telephone to 01635 206360.

It is very important that you **provide the batch number** of the product used by the patient at the time of onset of the AE when reporting the adverse event.



Please also report AEs to the Medicines and Healthcare products Regulatory Agency (MHRA) via the Yellow Card reporting system (<http://yellowcard.mhra.gov.uk>).

For further information please contact Surecall Baxter Medical Information on 01635 206345.

Sincerely,

A handwritten signature in black ink, appearing to read 'D Whitehouse', with a long, sweeping underline stroke.

David Whitehouse
Business Unit Director
Renal Division
Baxter Healthcare