



**IMPORTANT NEW
SAFETY INFORMATION**

Dr. Almath Spooner
Human Products Monitoring Department
Irish Medicines Board
Kevin O'Malley House
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Earlsfort Terrace
Dublin 2

25th January 2011

Dear Dr. Spooner,

NEW INFORMATION: Dianeal, Extraneal, Nutrineal – potential presence of elevated endotoxin levels and risk of aseptic peritonitis

As a follow up to our previous communication dated 17 December 2010 concerning the potential presence of endotoxin in some batches of the peritoneal dialysis (PD) solutions Dianeal, Extraneal and Nutrineal and an increased risk of aseptic peritonitis we would like to update you on the following:

Important advice

Batches of Dianeal, Extraneal and Nutrineal (manufactured in Castlebar Ireland) considered potentially affected by presence of endotoxin remain on the market as there is currently not enough supply of unaffected products to meet patient needs. However, corrective measures are being implemented, and the risk of receiving endotoxin is very limited as only a small percentage of bags are likely to be affected.

New unaffected Dianeal, Extraneal and Nutrineal PD solutions will be temporarily imported into the EU from alternative Baxter manufacturing sites outside the EU (Canada, US, Singapore and Turkey) in order to promptly replace supply from Ireland. While these are similar in composition and presentation to the products from Castlebar, the necessarily short timescale for their introduction means that they will be supplied as exempt (unauthorised) products. This temporary change over will be needed for several months while the manufacturing problem at Castlebar is fully addressed. During the next few weeks, the supply situation will remain critical.



Information on the exact imported product and patient instructions will be provided with each product.

Use of imported PD solutions when available should be prioritised over the solutions produced at Baxter's Castlebar facility, especially to vulnerable patient populations, including Extraneal patients with otherwise uncontrollable fluid overload.

The supply situation will be rapidly evolving and Baxter will provide further information on a regular basis.

Advice for existing patients

For existing PD patients alternative PD therapies, PD solutions including Physioneal or dialysis methods should be considered. Physicians should weigh the risks and benefits of continuing the use of Dianeal, Extraneal and Nutrineal PD solutions that are potentially affected by this issue.

In both CAPD and APD patients, consider replacement of Dianeal and Nutrineal with Physioneal for the short dwell.

Advice for new patients

New PD patients should preferably receive PD products known to be unaffected (i.e. non-Baxter products or imported Baxter products).

Please report all suspected adverse reactions

Please continue to report all potential adverse reactions with all peritoneal dialysis solutions.

We recommend using the adverse event reporting form that is attached. You are asked to send this marked for the attention of Baxter UK Pharmacovigilance at Baxter Healthcare Ltd, Wallingford Road, Compton, Newbury RG20 7QW, by email to vigilanceuk@baxter.com or by fax to +44 1635 206281 or to Surecall Baxter Medical Information on telephone +44 1635 206345.

Note: It is very important that you provide the batch number of the suspected product(s) used by the patient when completing the form.





Further information on imported (non-Castlebar) products

The imported replacement products will:

- Have the same characteristics as the usual supply of Dianeal, Extraneal and Nutrineal, and are not affected by the endotoxin issue.
- Be matched for connection technology with the connections currently used by your patients.
- Include simple training material for use by patients

You will be informed by your local Baxter team of the exact imported product for your patients.

Supplies of new Dianeal, Extraneal and Nutrineal PD solutions should be prioritised for vulnerable populations, specifically patients requiring Extraneal including those with otherwise uncontrollable fluid overload.

Further information

For further information please contact the Baxter Clinical Nurse Specialist (primary contact) or Surecall Baxter Medical Information on +44 1635 206345.

Sincerely,

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