21 March 2005

NOTICE TO HOSPITALS and PD CLINICS

To: Hospital Chief of Medical Staff and PD Clinic staff

Please distribute to the relevant departments of nephrology, emergency medicine, Internal Medicine, Endocrinology, Pharmacy, Diabetic Education units, and other involved professional staff, and post this NOTICE in your institution.

Subject: Association of Extraneal™ with falsely elevated blood glucose monitor readings with use of non-specific glucose monitoring systems

Baxter Corporation would like to remind you about important safety information involving peritoneal dialysis patients (PD) who use EXTRANEAL™ (Icodextrin, Sodium chloride, Sodium lactate, Calcium chloride, Magnesium chloride Peritoneal Dialysis Solution) AND use blood glucose monitoring systems.

In 1999, Health Canada approved the sale and marketing of a new solution for peritoneal dialysis (EXTRANEAL™). EXTRANEAL™ contains Icodextrin which is a large molecular weight glucose polymer used in peritoneal dialysis solutions due to its high ultra filtration capacity. From the peritoneal cavity, Icodextrin can move into the systemic blood stream where it is metabolized by serum amylase into maltose (a glucose dimer) and other oligosaccharides. The accumulation of blood maltose via Icodextrin metabolism is cause for concern in individuals who use blood glucose monitoring systems that are not glucose specific. Recently Baxter has become aware of incidents involving the interaction of Icodextrin with non-specific glucose monitoring systems that produce falsely elevated blood glucose results and thought it important that we remind you of the following:

Patients receiving EXTRANEAL™ for peritoneal dialysis therapy may have falsely elevated blood glucose results when using particular blood glucose monitoring systems. Blood glucose monitoring systems using the enzyme glucose dehydrogenase pyrroloquinolinequinone (GDH-PQQ) will result in a falsely elevated glucose reading. A false high blood glucose reading could cause a patient to get more insulin than they need. Furthermore, a blood glucose reading with these monitors within the normal range in a patient on EXTRANEAL™ may be masking low blood sugar. This would cause a patient or healthcare professionals not to take the appropriate steps to bring the blood sugar into a normal range. These particular glucose monitors must not be used for patients using EXTRANEAL™.

EXTRANEAL™ metabolites (maltose, maltotriose, or maltotetraose) result in elevated maltose levels in patients using EXTRANEAL™. This high level of maltose is an expected and normal response in EXTRANEAL™ patients. These elevated levels have been observed to interfere with the GDH-PQQ enzyme pathway and lead to a falsely elevated blood glucose reading.1, 2 Blood glucose measurement must be done with a glucose specific method (monitor and test strips) to avoid interference by maltose release from EXTRANEAL™. GDH-PQQ based methods must not be used. Because manufacturers of glucose monitors and test strips may change assay methods, it is not possible for Baxter to identify or provide a comprehensive list of products that utilize GDH-PQQ to our patients.
If your facility or patient uses a system employing this enzyme, you must find an alternative method to test blood glucose for patients using EXTRANEAL™. The test method chosen must use a glucose-specific enzyme, such as glucose oxidase or hexokinase.

When determining appropriate measures for your facility’s staff and procedures, we suggest the following to be considered:

- Determine appropriate training measures for staff to increase awareness of this issue.
- Review procedures to follow in an emergency situation, especially with patients who are known diabetics and/or unconscious.
- Ensure that patients using EXTRANEAL™ (icodextrin) use only glucose-specific monitoring systems that are not subject to interference for icodextrin metabolites. Blood glucose monitoring systems using the enzyme GDH-PQQ should not be used. If in doubt about a specific glucose monitoring system’s susceptibility to this interference, contact the manufacturer.
- Encourage user of EXTRANEAL™ (icodextrin) to identify themselves with MedicAlert® products and to inform others involved in their care of this medical information.
- Support all blood glucose monitoring systems with a central laboratory reference method in cases where the glucose monitor readings do not coincide with the clinical picture.

Should you have additional questions about EXTRANEAL™ please contact Baxter's EXTRANEAL™ information line at 1-800-925-7568.

Sincerely,

Pam Bobbette
Vice President Quality
Baxter Corporation

References:
