

ESRD NETWORK 13



Serving Arkansas, Louisiana & Oklahoma Renal Communities

September 22, 2008

MEMORANDUM:

FOR IMMEDIATE ATTENTION / ACTION

To: Dialysis Unit Nurse Managers / Medical Directors / Administrators
(Arkansas, Louisiana, and Oklahoma)

From: Linda Duval, RN, BSN [405.948.2244 or lduval@nw13.esrd.net]
Director, Quality Improvement

Subject: 1) FDA Notice: Icodextrin (EXTRANEAL) and point of care glucose monitoring
A Dangerous Drug-Device Interaction

The Network is required to distribute information regarding Federal Drug Administration (FDA) alerts, dialysis recalls, etc. that potentially affect ESRD facilities and/or patients. This information is specific to peritoneal dialysis patients and their care. The following information is provided from the FDA accordingly.

FDA continues to receive report of adverse events, including fatalities, related to a drug-device interaction associated with the use of icodextrin (Extraneal), a peritoneal dialysis solution, and certain point-of-care glucose monitoring devices that do not use a glucose-specific test strip. Icodextrin is broken down into maltose *in vivo*. Some test strips used with portable glucose meters cannot differentiate between maltose, glucose and other sugars as they use methods that are not glucose-specific. The test strips associated with this drug-device interaction use glucose dehydrogenase pyrroloquinolinequinone (GDH-PQQ) or glucose-dye-oxidoreductase (GDO) as reagents. Examples of meters currently using these types of test strips include the Accu-Chek (manufactured by Roche) and FreeStyle (manufactured by Abbott) models. We urge healthcare providers and patients to refer to test strip package inserts or to consult the glucose monitoring device and test strip manufacturer(s) to confirm the glucose methodology in any system that is to be used for monitoring patients receiving icodextrin.[†] A list of toll free numbers for glucose monitor and test strip manufacturers is available at the **Baxter Renal Clinical Help Line (1-888-RENAL-HELP)**.

Due to the presence of maltose in the blood of a patient receiving Extraneal therapy, the use of test strips that are not glucose-specific provides falsely elevated glucose readings. Falsely elevated blood glucose readings may lead to inappropriate insulin administration, which has caused hypoglycemia, coma, and death. Additionally, cases of true hypoglycemia can go untreated if masked by falsely elevated glucose readings. As indicated in the *Warning* section of Extraneal's label, blood glucose measurement in patients receiving Extraneal must be done with a glucose-specific method (monitor and test strips) to avoid interference by maltose released from Extraneal. Glucose-specific methods (i.e., methods that are *not* affected by this interaction) include those that use glucose oxidase, glucose hexokinase, glucose dehydrogenase nicotinic adenine dinucleotide (GDH-NAD), or flavin adenine dinucleotide glucose dehydrogenase (FAD-GDH) based reagents.

This drug-device interaction was identified prior to approval of icodextrin and it is described in product labeling. Several safety measures, including patient/healthcare professional education, have been undertaken by the manufacturer. Because FDA continues to receive reports of this adverse event, we are highlighting this drug-device interaction in additional FDA communications to the public. For a complete discussion on this drug-device interaction, including detailed case reports, see the [recent FDA communiqué](#) in the Institute for Safe Medication Practices' (ISMP) publication Medication Safety Alert.

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Mission Statement: "To assess and improve the quality of care provided to individuals with End Stage Renal Disease."

Footnote

† A comprehensive list of FDA-cleared GDH-PQQ and GDO blood glucose monitoring systems is not provided because any such list may become outdated or inadvertently exclude systems distributed under multiple trade names. Note, some product lines include test strips that use more than one type of enzyme methodology. Further, manufacturers of GDH-PQQ systems currently on the market may subsequently change to non-GDH-PQQ methodology. Thus, patients and healthcare providers should consult the test strip package insert or contact the glucose monitoring device and test strip manufacturer(s) for information on the type of methodology used.

Relevant Links and Related Information

FDA Patient Safety News (Avoiding Glucose Monitoring Errors in Patients Receiving Other Sugars):

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/psn/transcript.cfm?show=55#2>

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/psn/transcript.cfm?show=48#4>

[FDA Center for Biologics Evaluation and Research \(Fatal Iatrogenic Hypoglycemia: Falsely Elevated Blood Glucose Readings with a Point-of-Care Meter Due to a Maltose-Containing Intravenous Immune Globulin Product\)](#)

[ISMP Medication Safety Alert \(Be aware of false glucose results with point-of-care testing\)](#)

The Network 13 Web site (<http://www.network13.org>) also has this information as provided by the FDA. In the event that you do not have Internet capability, please contact the Network office and the applicable documents can be faxed to you. We will continue to provide updates as information is received in the Network office. Thanks for your time and attention.

Cc: Crystal Russell, Project Officer, CMS RO VI
Sandra Woodruff, MSPH, Executive Director