WARNING
ATTENTION HEALTH CARE PROFESSIONAL

Potential For Incorrect Blood Glucose Reading in Peritoneal Dialysis (PD) Patients

Dear Health Care Professional,

Baxter Healthcare Corporation would like to notify you of Important Safety Information involving all patients who use **Extraneal** (icodextrin) peritoneal dialysis (PD) solution and who may require the use of blood glucose monitors and test strips.

You are treating a patient using **Extraneal**. When checking blood glucose levels, use laboratory-based methods or verify the point-of-care (POC) glucometer and test strips are compatible for use in patients using **Extraneal**.

Extraneal or its by-products, such as maltose, can cause some types of glucose monitors and test strips to give falsely elevated blood glucose readings. This includes glucose monitors and test strips commonly used at hospitals and by emergency medical personnel.

Extraneal can cause falsely elevated blood glucose readings for up to 14 days after its last use, regardless of a patient's diabetic status.

If your hospital uses electronic medical records, the potential for interference with blood glucose monitors and test strips needs to be entered in a prominent field.

WHAT ARE THE POTENTIAL RISKS ASSOCIATED WITH HAVING A "FALSELY ELEVATED BLOOD GLUCOSE READING?"

SITUATION A: A falsely elevated blood glucose reading may lead to the erroneous diagnosis of hyperglycemia.

POTENTIAL RISK — A falsely elevated blood glucose reading could cause you or another clinician to administer insulin to the PD patient that is not needed.

SITUATION B: A falsely elevated blood glucose reading may mask true hypoglycemia.

POTENTIAL RISK — A falsely elevated blood glucose reading could cause you or another clinician to assume that a PD patient's blood glucose level is normal when their true (hospital central lab) blood glucose level may be dangerously low. This could lead you or another clinician to NOT take the appropriate steps needed to bring the patient's blood glucose level back into a normal range.

Always contact the device manufacturer for current information regarding compatibility and intended use of the device in the dialysis patient population.

For further information, refer to **Extraneal** Prescribing Information or visit **www.glucosesafety.com**.

We hope this information is helpful to you. If you have additional questions about **Extraneal**, please contact Baxter's Renal Clinical Helpline at 1-888-736-2543 (option 1).

Sincerely,

Baxter Healthcare

Please see full Important Safety Information, including boxed warning, on reverse side and enclosed Full Prescribing Information.

EXTRANEAL (icodextrin) Peritoneal Dialysis Solution Indications and Important Risk Information (IRI)

Indications

EXTRANEAL (icodextrin) is indicated for a single daily exchange for the long (8- to 16- hour) dwell during continuous ambulatory peritoneal dialysis (CAPD) or automated peritoneal dialysis (APD) for the management of end-stage renal disease. EXTRANEAL is also indicated to improve (compared to 4.25% dextrose) long-dwell ultrafiltration and clearance of creatinine and urea nitrogen in patients with high average or greater transport characteristics, as defined using the peritoneal equilibration test (PET).

Important Risk Information:

- EXTRANEAL is contraindicated in patients with a known allergy to cornstarch or icodextrin, in patients with maltose or isomaltose intolerance, in patients with glycogen storage disease, and in patients with severe lactic acidosis.

- When measuring blood glucose levels in patients using EXTRANEAL, do not use blood glucose monitoring devices using glucose dehydrogenase pyrroloquinolinequinone (GDH-PQQ)-, glucose-dye-oxidoreductase (GDO)-, and some glucose dehydrogenase flavin-adenine dinucleotide (GDH-FAD)-based methods because these systems may result in falsely elevated glucose readings (due to the presence of maltose). Falsely elevated glucose readings have led patients or health care providers to withhold treatment of hypoglycemia or to administer insulin inappropriately leading to unrecognized hypoglycemia. Falsely elevated glucose levels may be measured up to two weeks following cessation of EXTRANEAL therapy when GDH-PQQ-, GDO-, and GDH-FAD-based blood glucose monitors and test strips are used. Additionally, other glucose-measuring technologies, such as continuous glucose monitoring systems, may or may not be compatible with EXTRANEAL. Always contact the device manufacturer for current information regarding compatibility and intended use of the device in the dialysis patient population.

- EXTRANEAL is intended for intraperitoneal administration only. Not for intravenous or intra-arterial administration. Aseptic technique should be used throughout the peritoneal dialysis procedure.

- Encapsulating peritoneal sclerosis (EPS), sometimes fatal, is a complication of peritoneal dialysis therapy and has been reported in patients using EXTRANEAL.

- Serious hypersensitivity reactions to EXTRANEAL have been reported such as toxic epidermal necrolysis, angioedema, serum sickness, erythema multiforme and vasculitis. Anaphylactic or anaphylactoid reactions may occur. If a serious reaction is suspected, discontinue EXTRANEAL immediately and institute appropriate therapeutic countermeasures.

- Overinfusion of peritoneal dialysis solution volume into the peritoneal cavity may be characterized by abdominal distention, feeling of fullness and/or shortness of breath. Drain the peritoneal dialysis solution from the peritoneal cavity to treat overinfusion.

- Patients with insulin-dependent diabetes may require modification of insulin dosage following initiation of treatment with EXTRANEAL. Monitor blood glucose and adjust insulin, if needed.

- Peritoneal dialysis may affect a patient's protein, water-soluble vitamin, potassium, sodium, chloride, bicarbonate, and magnesium levels and volume status. Monitor electrolytes and blood chemistry periodically. Monitor fluid status to avoid hyper- or hypovolemia and potentially severe consequences including congestive heart failure, volume depletion, and hypovolemic shock. Abnormalities in any of these parameters should be treated promptly under the care of a physician.

- In clinical trials, the most frequently reported adverse events occurring in ≥10% of patients and more common in EXTRANEAL PD solution patients than in control patients, were peritonitis, upper respiratory infection, hypertension, and rash. The most common treatment-related adverse reaction for EXTRANEAL PD solution patients was skin rash.

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