Attention Hospital Physician

WARNING

Potential For Incorrect Blood Glucose Reading

Dear Hospital Physician,

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

Patients using EXTRANEAL (icodextrin) peritoneal dialysis solution may have incorrect blood glucose results when using particular blood glucose monitors and test strips.

ONLY use glucose monitors and test strips that are glucose-specific. These methods are common in clinical laboratories. Contact the manufacturer of the glucose monitors and test strips to determine the method that is used. For further information, visit www.glucosesafety.com.

The term "glucose-specific" applies to monitors or test strips that are not affected by the presence of maltose or certain other sugars. Because **Extraneal** (icodextrin) PD solution results in elevated blood levels of maltose, only glucose-specific monitors and test strips should be used. Glucose-specific monitors and test strips include glucose oxidase (GOD), hexokinase, glucose dehydrogenase with nicotinamide adenine dinucleotide (GDH-NAD), or glucose dehydrogenase with flavin-adenine dinucleotide (GDH-FAD) based methods.

DO NOT use monitors or test strips that utilize the enzyme glucose dehydrogenase pyrroloquinolinequinone (GDH PQQ) or glucose-dye-oxidoreductase. Maltose interferes with these glucose monitors and test strips, which may result in a falsely elevated blood glucose reading. This may mask true hypoglycemia or lead to the erroneous diagnosis of hyperglycemia. A blood glucose reading with these monitors within the normal range in a patient on **Extraneal** (icodextrin) PD solution may mask low blood sugar. This would cause a patient or health care professional not to take the appropriate steps to bring the blood sugar into a normal range. A falsely elevated blood glucose reading could cause a patient to get more insulin than needed. Both of these situations can lead to life-threatening events, including loss of consciousness, coma, neurological damage or death.

Additional considerations for patients who use EXTRANEAL (icodextrin) PD solution include:

1. Discontinuing **Extraneal** (icodextrin) PD solution use will not immediately address the risk for the potential interference with glucose monitors. Plasma levels of icodextrin and its metabolites require a minimum of fourteen days to become undetectable.
2. To determine what type of method is used for monitoring glucose levels, review the labeling for BOTH the glucose monitor and the test strips used. If in doubt, contact the manufacturer of the glucose monitors and test strips to determine the method that is used.
3. If your hospital uses electronic medical records, the above information describing the potential for interference with blood glucose monitors or test strips needs to be entered in a suitable field that is readily apparent to all users.

For further information, refer to **Extraneal** (icodextrin) PD solution prescribing information enclosed or visit www.glucosesafety.com.

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

Sincerely,

James A. Sloand, MD
Medical Affairs, Baxter Healthcare Corporation

Please see Important Risk Information on reverse side and enclosed Full Prescribing Information.

INDICATION

Extraneal (icodextrin) Peritoneal Dialysis (PD) solution 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 (ESRD). **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 (icodextrin) Peritoneal Dialysis (PD) Solution

Dangerous Drug-Device Interaction

Only use glucose-specific monitors and test strips to measure blood glucose levels in patients using **Extraneal** (icodextrin) PD Solution. Blood glucose monitoring devices using glucose dehydrogenase pyrroloquinolinequinone (GDH PQQ) or glucose-dye-oxidoreductase (GDO)-based methods must not be used. Use of GDH PQQ or GDO based glucose monitors and test strips has resulted in falsely elevated glucose readings due to the presence of maltose and has led patients or health care providers to withhold treatment of hypoglycemia or to administer insulin inappropriately. Both of these situations have resulted in unrecognized hypoglycemia, which has led to loss of consciousness, coma, permanent neurological damage, and death. Plasma levels of **Extraneal** and its metabolites return to baseline within approximately 14 days following cessation of **Extraneal** administration. Therefore falsely elevated glucose levels may be measured up to two weeks following cessation of **Extraneal** therapy when GDH PQQ or GDO-based blood glucose monitors and test strips are used.

Because GDH PQQ and GDO-based blood glucose monitors may be used in hospital settings, it is important that the health care providers of peritoneal dialysis patient using **Extraneal** carefully review the product information of the blood glucose testing system, including that of test strips, to determine if the system is appropriate for use with **Extraneal** (icodextrin) PD Solution.

To avoid improper insulin administration, educate patients to alert health care providers of this interaction whenever they are admitted to the hospital.

Information regarding glucose monitor and test strip methodology can be obtained from their manufacturers. For a list of toll free numbers for glucose monitor and test strip manufacturers, please contact the Baxter Renal Clinical HelpLine 1-888-RENAL-HELP or visit www.glucosesafety.com.

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

Extraneal is not for intravenous injection.

Patients with insulin-dependent diabetes may require modification of insulin dosage following initiation of treatment.

A patient's volume status should be carefully monitored to avoid hyper- or hypovolemia and potentially severe consequences including congestive heart failure, volume depletion and hypovolemic shock. An accurate fluid balance record must be kept and the patient's body weight monitored.

In clinical trials, the most frequently reported adverse events occurring in ≥ 5% of patients, and more common in **Extraneal** patients than in control patients, were peritonitis, upper respiratory infection, hypertension, and rash. The most common treatment-related adverse event for **Extraneal** patients was skin rash. Additional adverse reactions have been reported in the post-marketing setting and are detailed in the full prescribing information.

General Peritoneal Dialysis-Related

Encapsulating Peritoneal Sclerosis (EPS) is a known, rare complication of peritoneal dialysis therapy. EPS has been reported in patients using peritoneal dialysis solutions including **Extraneal**. Infrequent but fatal outcomes have been reported.

Aseptic technique should be used throughout the peritoneal dialysis procedure to reduce the possibility of infection, such as peritonitis.

Fluid status, hematologic indices, blood chemistry, and electrolyte concentrations, including calcium, potassium, sodium, magnesium and bicarbonate, should be monitored periodically. Abnormalities in any of these parameters should be treated promptly under the care of a physician.

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

Treatment should be initiated and monitored under the supervision of a physician knowledgeable in the management of patients with renal failure.

Please see full prescribing information.