

# WARNING

## ATTENTION HOSPITAL PHYSICIAN

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

#### Dear Hospital Physician,

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** (icodextrin) peritoneal dialysis (PD) solution. 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** PD Solution.

**Extraneal** (icodextrin) PD Solution 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** PD Solution 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.

■ **BOTH** of these situations can potentially cause a life-threatening event, such as:

- Loss of consciousness
- Coma
- Permanent neurological problems
- Death

For further information, refer to **Extraneal** (icodextrin) PD Solution Prescribing Information enclosed or visit [www.glucosesafety.com](http://www.glucosesafety.com).

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

Sincerely,

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

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

## Indications

**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** solution 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:

### WARNING: UNRECOGNIZED HYPOGLYCEMIA RESULTING FROM DRUG-DEVICE INTERACTION

- Only use glucose-specific monitors and test strips to measure blood glucose levels in patients using EXTRANEAL (icodextrin) Peritoneal Dialysis Solution. Blood glucose monitoring devices using glucose dehydrogenase pyrroloquinolinequinone (GDH-PQQ) or glucose-dye-oxidoreductase (GDO)-based methods must not be used. In addition, some blood glucose monitoring systems using glucose dehydrogenase flavin-adenine dinucleotide (GDH-FAD)-based methods must not be used. Use of GDH-PQQ, GDO, and GDH-FAD-based glucose monitors and test strips has resulted 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. 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 (icodextrin) and its metabolites return to baseline within approximately 14 days following cessation of EXTRANEAL (icodextrin) administration. Therefore falsely elevated glucose levels may be measured up to two weeks following cessation of EXTRANEAL (icodextrin) therapy when GDH-PQQ, GDO, and GDH-FAD-based blood glucose monitors and test strips are used.
- To avoid improper insulin administration, educate all patients to alert health care providers of this interaction particularly in hospital settings.
- The manufacturer(s) of the monitor and test strips should be contacted to determine if icodextrin or maltose causes interference or falsely elevated glucose readings. For a list of toll free numbers for glucose monitor and test strip manufacturers, please contact the Baxter Renal Clinical Help Line 1-888-RENAL-HELP or visit [www.glucosesafety.com](http://www.glucosesafety.com).
- Because of the risk of unrecognized hypoglycemia that could result from a drug-device interaction, EXTRANEAL is available only through a restricted program.

- **Extraneal** (icodextrin) 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 pre-existing severe lactic acidosis.
- **Extraneal** PD solution is intended for intraperitoneal administration only. Not for intravenous injection. 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** PD solution.
- Serious hypersensitivity reactions to **Extraneal** PD solution have been reported such as toxic epidermal necrolysis, angioedema, serum sickness, erythema multiforme and vasculitis. Anaphylactic or anaphylactoid reactions may occur. Stop the infusion immediately and drain the solution from the peritoneal cavity if any signs or symptoms of a suspected hypersensitivity reaction develop. Institute appropriate therapeutic countermeasures as clinically indicated.
- Effective use of **Extraneal** PD solution may be compromised in patients with abdominal conditions predisposing them to complications of peritoneal dialysis, including infection.
- 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** PD solution. 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  $\geq 10\%$  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 event for **Extraneal** PD solution patients was skin rash.
- Please see Package Insert for full Prescribing Information.