

**Important Risk Information**

**Dangerous 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, see **PRECAUTIONS/Drug/Laboratory Test Interactions**). 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.

Because GDH-PQQ, GDO, and GDH-FAD-based blood glucose monitors may be used in hospital settings, it is important that the health care providers of peritoneal dialysis patients using EXTRANEAL (icodextrin) 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).

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

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.glucozesafety.com](http://www.glucozesafety.com).

- 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
- Rarely, serious hypersensitivity reactions to EXTRANEAL have been reported, such as toxic epidermal necrolysis, angioedema, serum sickness, erythema multiforme and leukocytoclastic vasculitis. If a serious reaction is suspected, discontinue EXTRANEAL and institute appropriate treatment as clinically indicated
- 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  $\geq 10\%$  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. 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 PD solution. 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.**