

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.glucozesafety.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 $\geq 5\%$ 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.