

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 SAFETY INFORMATION

EXTRANEAL (icodextrin) Peritoneal Dialysis (PD) Solution

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.

Since falsely elevated glucose levels have been observed with blood glucose monitoring devices and test strips that use glucose dehydrogenase pyrroloquinolinequinone (GDH PQQ) or glucose-dye-oxidoreductase-based methods, these methods should not be used to measure glucose levels in patients administered EXTRANEAL. Falsely elevated glucose levels may mask true hypoglycemia or lead to the erroneous diagnosis of hyperglycemia and administration of more insulin than needed. Both of these situations can result in loss of consciousness, coma, neurological damage and death. The manufacturer(s) of the monitor and test strips should be contacted to determine if icodextrin or maltose causes interference or falsely elevated glucose results.

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 considered to be 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.

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.