



Important Safety Information

Peritoneal Dialysis Solution with 7.5% Icodextrin (EXTRANEAL)

- **Peritoneal Dialysis solution with 7.5% Icodextrin (EXTRANEAL)** is contraindicated in patients with a known allergy to cornstarch or icodextrin or in patients with glycogen storage disease
- 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 Peritoneal Dialysis solution with 7.5% Icodextrin (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**
- 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.
- Treatment should be initiated and monitored under the supervision of a physician knowledgeable in the management of patients with renal failure
- Patients with insulin-dependent diabetes may require modification of insulin dosage following initiation of treatment
- In clinical trials the most frequently reported adverse events occurring in $\geq 5\%$ of patients, and more common in Peritoneal Dialysis solution with 7.5% Icodextrin (**EXTRANEAL**) patients than in control patients, were peritonitis (26% vs 25%), upper respiratory infection (15% vs 13%), hypertension (13% vs 8%), and rash (10% vs 5%). The most common treatment-related adverse event for Peritoneal Dialysis solution with 7.5% Icodextrin (**EXTRANEAL**) patients was skin rash (5.5% vs 1.7%)
- Please see full prescribing information