

Important Safety Information

EXTRANEAL (icodextrin 7.5%) Peritoneal Dialysis Solution

- **EXTRANEAL** is contraindicated in patients with a known allergy to cornstarch or icodextrin or in patients with glycogen storage disease
- Not for intravenous injection
- **DO NOT use monitors or test strips that utilize the enzyme glucose dehydrogenase pyrroloquinolinequinone (GDH-PQQ) or glucose-dye-oxidoreductase methods. In addition, some but not all monitors or test strips that utilize a glucose dehydrogenase flavin-adenine dinucleotide (GDH-FAD) method should not be used. Use of these methods may result in falsely elevated blood glucose readings in patients using EXTRANEAL (icodextrin 7.5%) due to maltose interference. Falsely elevated blood glucose readings may mask true hypoglycemia or lead to the erroneous diagnosis of hyperglycemia, leading to life-threatening events. 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 **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 **EXTRANEAL** patients was skin rash (5.5% vs 1.7%)
- Please see full prescribing information