Therapeutic Indications

EXTRANEAL is recommended as a once daily replacement or a single Dextrose exchange as part of a CAPD or automated peritoneal dialysis (APD) regimen for the treatment of chronic renal failure, particularly for some categories of patients who have lost ultrafiltration on Dextrose solutions, because it can extend time on CAPD therapy in such patients.

Important Safety Information
EXTRANEAL (Icodextrin 7.5%) Peritoneal Dialysis Solution

O **EXTRANEAL** is contraindicated in patients with a known allergy to cornstarch or Icodextrin or in patients with glycogen storage disease.

O Not for intravenous injection.

O **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.**

O 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.

O Treatment should be initiated and monitored under the supervision of a physician knowledgeable in the management of patients with renal failure.

O Patients with insulin-dependent diabetes may require modification of insulin dosage following initiation of treatment.

O In clinical trials the most frequently reported adverse events occurring in ≥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%).

O Please see full prescribing information.

Important Safety Information For Patients

Icodextrin or its by-products, such as maltose, may cause some types of home glucose monitors and/or glucose test strips to give a **false high glucose reading**.

 You or your PD nurse must verify that your home glucose monitor(s) and glucose test strip(s) will provide an accurate reading when using **EXTRANEAL** (Icodextrin) by contacting the manufacturer of your glucose monitor(s) and glucose test strip(s).

 When you contact the glucose monitor(s) or test strip manufacturer, ask the following question, “Does Icodextrin or maltose interfere with my home glucose monitor or test strip results?”.

 You must notify your doctor and PD nurse before you change your home glucose monitor(s) or glucose test strip(s) from one product or another.

 You must inform your spouse or family member that you are using **EXTRANEAL.**

 If you are ever hospitalized or admitted to the emergency room, notify the hospital staff that you are using **EXTRANEAL** and that Icodextrin and maltose may give a false high glucose reading with some glucose monitors or test strips.

 If you have any questions concerning your home glucose monitor and/or glucose test results, please call the Manufacturer Customer Contact Number.

Name of glucose monitor(s) or glucose test strip(s)	Manufacturer	Manufacturer contact number	Does Icodextrin or maltose interfere with the glucose results? (Yes* or No)