PRESCRIBING INFORMATION - EXTRANEAL (ICODEXTRIN 7.5%)

Name and composition: Extraneal (Icodextrin 7.5%) solution for peritoneal dialysis. Each one litre contains: Icodextrin 75.0g, Sodium Chloride 5.4g, Sodium S-Lactate 4.5g, Calcium Chloride 0.257g, Magnesium Chloride 0.051g, Water for Injections. **Indications**: Once daily replacement for single glucose exchange as part of a continuous ambulatory peritoneal (CAPD) or automated peritoneal dialysis (APD) regimen for the treatment of chronic renal failure, particularly for patients who have lost ultrafiltration on glucose solutions. **Dosage and Route:** Intraperitoneal administration only. For use in the longest dwell period in CAPD or APD regimens. Adults and elderly - one exchange in each 24 hours. Safety and efficacy not established in children under 18 years. For adult patients of normal body size the instilled volume should not exceed 2.0L. Instill and drain solution at a rate patient finds comfortable. Warm to 37 degrees C if required for patient comfort using dry heat only. Dwell times typically 6-12 hours for CAPD and 14-16 hours for APD. For single use only. **Side effects:** *See Summary of Product Characteristics for detail. Common* - abdominal pain, asthenia, headache, tinnitus, hypertension, hypotension, hypovolaemia and dehydration, peripheral oedema, dizziness, rash, pruritus and skin exfoliation. *Unknown frequency*: thrombocytopenia, leucopenia, vasculitis, hypersensitivity, shock hypoglycaemia, hypoglycaemic coma, vision blurred, bronchospasm, inguinal hernia, Enhanced ultrafiltration, particularly in the elderly, may lead to dehydration, resulting in hypotension, dizziness and possible neurological symptoms. Hypoglycaemic episodes in diabetic patients (including hypoglycaemic coma and shock hypoglycaemia). Peritoneal reactions, including abdominal pain, cloudy effluent with or without infection. Anaphylactic/anaphylactoid reactions may occur. Stop infusion immediately and drain the solution from the peritoneal cavity if signs/symptoms of suspected hypersensitivity reaction develop. **Precautions**: Not recommended in acute renal failure. Rarely, serious hypersensitivity reactions have been reported (toxic epidermal necrolysis, angioedema, erythema multiforme and vasculitis). If a serious reaction is suspected discontinue Extraneal and treat symptoms as clinically indicated. Not recommended in pregnancy or lactation. Use with caution in patients with impaired respiratory function, recent aortic graft replacement, potassium deficiency or conditions which preclude normal nutrition. Treatment should be initiated under the direction of a nephrologist experienced in the use of peritoneal dialysis. Monitor patient hydration status and fluid balance closely. Monitor serum electrolytes periodically, especially serum potassium in patients receiving cardiac glycosides. Monitor for occurrence of lactic acidosis before initiation and during treatment with Extraneal. Transfer from a glucose based PD solution to Extraneal may necessitate adjustment of insulin dose in diabetic patients. Monitor blood glucose with a glucose-specific method to prevent maltose interference. Do not use glucose dehydrogenase pyrroloquinolinequinone (GDH PQQ), or glucose-dye-oxireductase-based methods. Glucose dehydrogenase flavin-adenine dinucleotide (GDH-FAD) methods have resulted in falsely elevated glucose readings due to the presence of maltose. Use of such methods can lead to a falsely elevated blood glucose reading, which is associated with adverse patient outcomes including hypoglycaemia and hyperglycaemia. A decrease in serum amylase levels has been noticed with long term PD treatment with Extraneal. It is not known whether subnormal amylase levels may mask the rise in serum amylase seen in acute pancreatitis. Increase in serum alkaline phosphatase of approximately 20 IU/L has been seen, with individual cases associated with elevated serum glutamic oxaloacetic transaminase levels. Inspect drained fluid for fibrin or cloudiness, which may indicate infection or aseptic peritonitis. Take appropriate microbiological samples and initiate antibiotic treatment where infection is suspected. Withdraw Extraneal where other reasons for cloudy fluid have been excluded and evaluate result. Reintroduce under close supervision; if cloudy fluid recurs alternative PD therapy should be initiated. Employ aseptic technique throughout. Encapsulating peritoneal sclerosis (EPS) is a known, rare complication of PD therapy, and has been observed in patients using Extraneal. Fatal outcomes of EPS have been reported. **Contraindications**: Known allergy to starch based polymers (e.g. maize starch) or icodextrin. Maltose or isomaltose intolerance. Glycogen storage disease. Pre-existing severe lactic acidosis. Recent abdominal surgery or any condition that may compromise the integrity of the abdominal wall, abdominal surface, or intra-abdominal cavity. Documented loss of peritoneal function or extensive adhesions that compromise peritoneal function. **Interactions:** No formal interaction studies have been conducted with Extraneal. Potential interference with GDH-PQQ or glucose-dye-oxireductase-based blood glucose tests in diabetic patients. Use of some glucose monitors and test strips using glucose dehydrogenase flavin-adenine dinucleotide (GDH-FAD) methodology has resulted in falsely elevated

glucose readings due to the presence of maltose. (for details, please see summary of product characteristics). **Overdose**: Overinfusion may lead to abdominal distension, feeling of fullness, shortness of breath. Treatment involves draining excess Extraneal from the peritoneal cavity. **Legal category:** POM. **Basic NHS price:** FPB5270 2.5 litre (twin bag) £16.02, FPB5268C 2 litre (twin bag) £14.78, FPB4954R 2.5 litre (single bag) £13.55, FPB4938RC 2 litre (single bag) £12.32. Marketing Authorisation Number and Holder: PL 00116/0266. Baxter Healthcare Limited, Caxton Way, Thetford, Norfolk IP24 3SE. **Date of preparation:** April 2018