PRESCRIBING INFORMATION - EXTRANEAL (ICODEXTRIN 7.5% w/v)

Name and composition: Extraneal (Icodextrin 7.5%) solution for peritoneal dialysis. Each one litre contains: Icodextrin 75.0g, Sodium Chloride 5.4g, Sodium 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. Not for intravenous injection. 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 instilled volume should not exceed 2 liters. For larger patients fill volume of 2.5 liters may be used. Instill and drain solution at a rate patient finds comfortable. Dwell times typically 6-12 hours for CAPD and 14-16 hours for APD. **Side effects:** *See Summary of Product Characteristics for detail.* Common – Dehydration, hypovolaemia, dizziness, headache, tinnitus, hypotension, hypertension, abdominal pain, rash (including macular, popular, erythematous), pruritus, skin exfoliation, peripheral oedema & asthenia. Hypersensitivity-type reactions have been reported in patients using extraneal including bronchospasm. Hypoglycaemic episodes in diabetic patients (including hypoglycaemic coma and shock hypoglycaemia). Peritoneal reactions, including abdominal pain, cloudy effluent with or without infection. Serious - leukocytosis, thrombocytopenia, leucopenia, pulmonary oedema, inguinal hernia, periorbital oedema, abnormal liver function tests. 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 some patients using Extraneal as part of their PD therapy. Infrequently, fatal outcomes have been reported with Extraneal. Rarely, serious hypersensitivity reactions to Extraneal have been reported such as toxic epidermal necrolysis, angioedema, erythema multiforme and vasculitis. Anaphylactic/anaphylactoid reactions may occur. If a serious reaction is suspected, discontinue Extraneal and institute appropriate treatment as clinically indicated. **Precautions**: Not recommended in acute renal failure. Not recommended in pregnancy or lactation. Use with caution in patients with impaired respiratory function, potassium deficiency or conditions which preclude normal nutrition. Patients with elevated lactate levels should use lactate-containing peritoneal dialysis solutions with caution. Treatment should be initiated under the direction of a nephrologist experienced in the use of peritoneal dialysis. Transfer from a glucose based PD solution to Extraneal may require 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. 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 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 SGOT 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. **Contraindications**: Known allergy to starch based polymers (e.g. maize starch) or icodextrin. Maltose or isomaltose intolerance. Glycogen storage disease, pre-existing severe lactic acidocis, uncorrectable mechanical defects that prevent effective PD or increase the risk of infection, documented loss of peritoneal function or extensive adhesions that compromise peritoneal function. **Interactions:** Potential interference with GDH-PQQ or glucose-dye-oxireductase-based blood glucose tests in diabetic patients. Also, the 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). Blood concentration of dialysable medicinal product may be reduced during dialysis. Plasma levels of potassium in patients using cardiac glycosides must be carefully monitored as there is a risk of digitalis

intoxication. Patients with conditions that increase the risk of lactic acidosis or receive treatment with drugs such as metformin and nucleoside/nucleotide reverse transcriptase inhibitors (NRTIs) must be monitored for occurrence of lactic acidosis before commencing and during treatment with lactate based peritoneal dialysis solutions. **Overdose**: No data available. **Legal category:** POM. **Marketing Authorisation Number and Holder:** PA 167/088/001. Baxter Healthcare Ltd, Caxton Way, Thetford, Norfolk IP24 3SE, UK. **Date of preparation June 2016.** Further information is available on request.