PRESCRIBING INFORMATION - PHYSIONEAL 35 AND 40 SOLUTIONS FOR PERITONEAL DIALYSIS in Viaflex or Clear-Flex containers

Name and composition:

	Physioneal 35 Glucose			Physioneal 40 Glucose		
	1.36% w/v / 13.6 mg/ml	2.27% w/v / 22.7 mg/ml	3.86% w/v / 38.6 mg/ml	1.36% w/v / 13.6 mg/ml	2.27% w/v / 22.7 mg/ml	3.86% w/v / 38.6 mg/ml
	g/L					
Glucose monohydrate	15.0	25.0	42.5	15.0	25.0	42.5
equivalent to Anhydrous Glucose	13.6	22.7	38.6	13.6	22.7	38.6
Sodium Chloride	5.67	5.67	5.67	5.38	5.38	5.38
Calcium Chloride Dihydrate	0.257	0.257	0.257	0.184	0.184	0.184
Magnesium Chloride Hexahydrate	0.051	0.051	0.051	0.051	0.051	0.051
Sodium Bicarbonate	2.10	2.10	2.10	2.10	2.10	2.10
Sodium Lactate	1.12	1.12	1.12	1.68	1.68	1.68

The pH of the final solution after mixing is 7.4. The number “35” specifies the buffer concentration of Physioneal 35 solution (10 mmol/l of lactate + 25 mmol/l of hydrogen carbonate = 35 mmol/l.) The number "40" specifies the buffer concentration of Physioneal 40 solution (15 mmol/l of lactate + 25 mmol/l of hydrogen carbonate = 40 mmol/l). **Indications**: Whenever peritoneal dialysis is employed, including: acute and chronic renal failure, severe water retention; severe electrolyte imbalance, drug intoxication with dialysable substances, when a more adequate therapeutic alternative is not available. Physioneal hydrogen carbonate/lactate based peritoneal dialysis solutions are particularly indicated in patients in whom solutions based on lactate buffer only, with a low pH, cause abdominal inflow pain or discomfort. **Dosage and Route:** For intraperitoneal administration only. Mode, frequency, exchange volume, duration of dwell and length of dialysis should be selected by the physician. On average, 4 to 7 exchanges of 2000 to 2500 ml per day are recommended. The safety and efficacy of Physioneal in paediatric patients have not been established. Only use in paediatric patients after careful risk-benefit analysis. Use of physioneal in Clear-Flex containers not recommended for children requiring <1600ml. To avoid the risk of severe dehydration, hypovolaemia and to minimise the loss of proteins, select the solution with the lowest level of osmolarity consistent with fluid removal requirements for each exchange. **Side effects:** *See Summary of Product Characteristics for detail. Common* – alkalosis, hypokalaemia, fluid retention, hypercalcaemia, hypertension, peritonitis, oedema, asthenia, weight increase. *Uncommon and unknown* - Peritoneal membrane failure, encapsulating sclerosing peritonitis, cloudy peritoneal effluent, eosinophilia, lactic acidosis, dyspnoea, angioedema. Procedure related problems: bacterial peritonitis, catheter site infection, catheter related complication. **Precautions**: Physioneal must not be used for intravenous infusion. Improper clamping or priming sequence may result in infusion of air into the peritoneal cavity, with abdominal pain and/or peritonitis. In cases of infusion of unmixed solution the patient should immediately drain the solution and use a newly mixed bag. Not recommended during pregnancy or in women of childbearing age not using contraception. Decision to discontinue breastfeeding or Physioneal therapy must be made depending on relative benefit to mother and child. Caution in abdominal conditions or other conditions including aortic graft replacement and severe pulmonary disease. Encapsulating Peritoneal Sclerosis has been reported in some patients using Physioneal. If peritonitis occurs, base choice and dose of antibiotics on identification and sensitivity studies. Monitor lactate in patients with elevated lactate levels or at increased risk of lactic acidosis. Monitor serum potassium in patients taking cardiac glycosides. Safety and efficacy not established in paediatric patients. Monitor fluid balance and weight. Plasma hydrogen carbonate levels above 30 mmol/L, risk of metabolic alkalosis. Protein, amino acids and water soluble vitamins may need replacement. Over infusion may cause abdominal distension/pain and/or shortness of breath. Excessive use may result in excessive water removal. Physioneal does not contain potassium. Serum Electrolytes concentration, blood chemistry, lipid parameters and haematological parameters should be monitored periodically. Caution in the use of a solution containing 1.25mmol/l calcium such as Physioneal 40 in patients with secondary hyperparathyroidism. In diabetes, blood glucose levels should be monitored and insulin dose adjusted as required. Improper clamping or priming sequence may result in infusion of air into the peritoneal cavity, which may

result in abdominal pain and/or peritonitis. All internal seals must be broken and the product thoroughly mixed prior to administration. Use with caution in patients with known allergy to maize/maize products. Stop infusion immediately if hypersensitivity signs/symptoms or suspected hypersensitivity develops and use appropriate therapeutic countermeasures. **Contraindications**: Hypersensitivity to active substance or excipients. Uncorrectable mechanical defects preventing effective PD or increase risk of infection. Loss of peritoneal function, extensive adhesions compromising peritoneal function. **Interactions:** 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. Potassium supplements may be necessary. **Overdose**: Possible consequences of overdose include hypervolaemia, hypovolaemia, electrolyte disturbances or hyperglycaemia in diabetic patients. **Legal category:** POM

Description	**NHS Price**
Physioneal 35 Solo spectrum (twin bag) 2.0 litre (1.36%, 2.27%, 3.86% glucose)	£8.13
Physioneal 35 System II (Single Bag) 2.5 litre (1.36%, 2.27%, 3.86% glucose)	£7.16
Physioneal 40 Solo spectrum (twin bag) 2.0 litre (1.36%, 2.27%, 3.86% glucose)	£8.13
Physioneal 40 Solo spectrum (twin bag) 2.5 litre (1.36%, 2.27%, 3.86% glucose)	£9.55
Physioneal 40 System II (single bag) 2.5 litre (1.36%, 2.27%, 3.86% glucose)	£7.16
Physioneal 35 Clear-Flex 5 litre bag (1.36%, 2.27%, 3.86% glucose)	£16.50
Physioneal 40 Clear-Flex 5 litre bag (1.36%, 2.27%, 3.86% glucose)	£16.50

Marketing Authorisation Number and Holder:

Physioneal 35 Glucose 1.36% w/v/13.6mg/ml	PL 58711/0010
Physioneal 35 Glucose 2.27% w/v/22.7mg/ml	PL 58711/0012
Physioneal 35 Glucose 3.86% w/v/38.6mg/ml	PL 58711/0014
Physioneal 40 Glucose 1.36% w/v/13.6mg/ml	PL 58711/0016
Physioneal 40 Glucose 2.27% w/v/22.7mg/ml	PL 58711/0018
Physioneal 40 Glucose 3.86% w/v/38.6mg/ml	PL 58711/0020
Physioneal 35 Glucose 1.36% w/v/13.6mg/ml Clear-Flex	PL 58711/0009
Physioneal 35 Glucose 2.27% w/v/22.7mg/ml Clear-Flex	PL 58711/0011
Physioneal 35 Glucose 3.86% w/v/38.6mg/ml Clear-Flex	PL 58711/0013
Physioneal 40 Glucose 1.36% w/v/13.6mg/ml Clear-Flex	PL 58711/0015
Physioneal 40 Glucose 2.27% w/v/22.7mg/ml Clear- Flex	PL 58711/0017
Physioneal 40 Glucose 3.86% w/v/38.6mg/ml Clear-Flex	PL 58711/0019

Vantive Limited, Wavertree Technology Park, 2 Wavertree Boulevard, Liverpool, L7 9PE, United Kingdom

Date of preparation: August 2024

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, FPB4945R 2.5 litre (single bag) £13.55, FPB4938RC 2 litre (single bag) £12.32. Marketing Authorisation Number and Holder: PL 58711/0005. Vantive Limited, Wavertree Technology Park, 2 Wavertree Boulevard, Liverpool, L7 9PE, United Kingdom. **Date of preparation:** August 2024

PRESCRIBING INFORMATION - NUTRINEAL PD4 with 1.1% amino acids

Name and composition: Nutrineal PD4 with 1.1% amino acids solution for peritoneal dialysis. Each litre contains: Tyrosine 300mg, Tryptophan 270mg, Phenylalanine 570mg, Threonine 646mg, Serine 510mg, Proline 595mg, Glycine 510mg, Alanine 951mg, Valine 1393mg, Methionine 850mg, Isoleucine 850mg, Leucine 1020mg, Lysine hydrochloride 955mg, Histidine 714mg, Arginine 1071mg, Calcium chloride dihydrate 184mg, Magnesium chloride hexahydrate 51mg, Sodium Lactate 4480mg, Sodium chloride 5380mg. **Indications**: Nutrineal is recommended as a non-glucose based peritoneal dialysis solution as part of a peritoneal dialysis regimen for the treatment of chronic renal failure patients. In particular, it is recommended for the malnourished peritoneal dialysis patients. **Dosage and Route:** For intraperitoneal administration only. Not for intravenous administration. Frequency of treatment and duration of dwell should be selected by the prescribing physician according to the patient's clinical status. Treatment should be re-evaluated after 3 months if no clinical or biochemical improvement noted in status of the patient. Recommended dietary allowance of protein is over or equal to 1.2g/kg for dialysed adults. Higher amounts may be necessary in several catabolic states. A 2.0L bag of Nutrineal provides 22g of amino acids - equivalent to 0.30g/kg/day for a 70kg adult dialysis patient. Children and adolescents: Safety and effectiveness in paediatric patients has not been established. If Nutrineal is used, the recommended posology is one peritoneal dialysis exchange per day. The clinical benefits of Nutrineal have to be balanced versus the risk of side effects in this patient category. For paediatric patients > 2 years old, a fill volume of 800 to 1400 ml/m2 to a maximum amount of 2000 ml, as tolerated, has been recommended. Fill volumes of 200 to 1000 ml/m2 are recommended in children less than 2 years of age. **Side Effects:** *See Summary of Product Characteristics for detail*. Very common: Acidosis, hypervolaemia, anorexia, nausea, vomiting, gastritis, asthenia, blood urea increased. Common: Infection, anaemia, hypokalaemia, hypovolaemia, depression, dyspnoea, abdominal pain. Other notable side effects with unknown frequency include hypersensitivity, sclerosing encapsulating peritonitis, peritonitis, cloudy peritoneal effluent, angioedema. Bacterial peritonitis is listed amongst undesirable effects associated with the PD procedure. **Precautions**: 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 Nutrineal. Safety and efficacy not assessed in children. Caution recommended in cases of 1) abdominal conditions, including disruption of the peritoneal membrane and diaphragm by surgery, from congenital anomalies or trauma until healing is complete, abdominal tumours, abdominal wall infection, hernias, faecal fistula, colostomy or iliostomy, frequent episodes of diverticulitis, inflammatory or ischemic bowel disease, large polycystic kidneys, or other conditions that compromise the integrity of the abdominal wall, abdominal surface, or intra-abdominal cavity; and 2) other conditions including aortic graft placement and severe pulmonary disease. If any signs or symptoms of a suspected hypersensitivity reaction develop, intraperitoneal administration of Nutrineal should be stopped immediately. Appropriate therapeutic measures should be instituted as clinically indicated. In cases of peritonitis, appropriate treatment should be undertaken. Monitor dietary protein intake, fluid and electrolyte balance, acid base balance and changes in nitrogen balance. Consider losses of dialysable medicinal products and water-soluble vitamins. Replacement therapy may be necessary. Strict aseptic technique must be used. Check clarity of the solution. Diabetic patients require careful monitoring of insulin dosage or hypoglycaemic treatment. In patients with secondary hyperparathyroidism, the benefits and risks of the use of dialysis solution with a low calcium content should be carefully considered as it might worsen hyperparathyroidism.

Contraindications: Known hypersensitivity to any amino acids in the product or to any of the excipients, serum urea level above 38 mmol/L, uraemic symptoms, metabolic acidosis, inborn errors of amino acid metabolism, liver insufficiency, severe hypokalaemia, 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:** Blood concentration of dialysable medicinal product may be reduced during dialysis. Plasma levels of potassium, calcium and magnesium should be monitored in patients treated with digitalis cardiac glycosides. **Overdose**: Overdose may result in hypervolaemia and electrolyte disturbances. Manage hypervolaemia by using hypertonic PD solutions and fluid restriction. Manage electrolyte disturbances according to the specific electrolyte identified by blood test. Hypokalaemia can be managed with potassium supplements, either orally or as additions to the PD solution. **Legal category:** POM. **Basic NHS price:** B9674R NUTRINEAL 1.1% 2.5L APD - £10.65, B9656 NUTRINEAL 1.1% 2L CAPD - £9.44. **Marketing Authorisation Number and Holder:** PL 58711/0007. Vantive Limited, Wavertree Technology Park, 2 Wavertree Boulevard, Liverpool, L7 9PE, United Kingdom. **Date of preparation:** August 2024