Abbreviated Summary of Product Characteristics
Nutrineal PD4 1.1% Amino Acids Solution for Peritoneal Dialysis

This abbreviated summary of product characteristics is intended for international use. Please note that it may differ from the licensed SPC in the country where you are practicing. Therefore, please always consult your country-specific SPC or package leaflet.

Name of the Medicinal Product
Nutrineal PD4 1.1% Amino Acids Solution for peritoneal dialysis

Qualitative and Quantitative Composition

Formula in mg/l	
Blend of Amino Acids:	
Alanine	951
Arginine	1071
Glycine	510
Histidine	714
Isoleucine	850
Leucine	1020
Lysine, HCl	955
Methionine	850
Phenylalanine	570
Proline	595
Serine	510
Threonine	646
Tryptophan	270
Tyrosine	300
Valine	1393
Sodium chloride	5380
Calcium chloride dihydrate	184
Magnesium chloride hexahydrate	51
Sodium (*S*)-lactate solution equivalent to Sodium (*S*)-lactate	4480
Composition in mmol/l	
Amino Acids	87.16
Na^+	132
Ca^{++}	1.25
Mg^{++}	0.25
Cl^-	105
$C_3H_5O_3^-$	40

Osmolarity 365 mOsmol/l
pH at 25°C 6.6

CLINICAL PARTICULARS
Therapeutic indications Nutrineal is recommended as 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.
Contraindications Nutrineal is contraindicated in patients with: hypersensitivity to the active substances or to any of the excipients listed in section 6.1, 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.
Special warnings and precautions for use Encapsulating peritoneal sclerosis (EPS) 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. Peritonitis: If peritonitis occurs, the choice and dosage of antibiotics should be based upon the results of identification and sensitivity studies of the isolated organism(s) when possible. Prior to identification of the involved organism(s), broad-spectrum antibiotics may be indicated. Hypersensitivity If any sign or symptom of a suspected hypersensitivity reaction develop, intraperitoneal administration of Nutrineal should be stopped immediately. Appropriate therapeutic measures should be instituted as clinically indicated. Metabolism of Nutrineal A portion of the amino acids in Nutrineal is converted to metabolic nitrogenous waste, such as urea. If dialysis is insufficient, the additional metabolic waste generated by the use of Nutrineal may lead to the appearance of uraemic symptoms such as anorexia or vomiting. Symptoms can be managed by reduction of the number of Nutrineal exchanges, or discontinuation of Nutrineal or an increased dialysis dose with a non-amino acid based solution. Use in patients with abdominal conditions Peritoneal dialysis should be done with caution in patients with: 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. General monitoring Significant losses of medicinal products (including water soluble vitamins) may occur during peritoneal dialysis. Replacement therapy should be provided as necessary. Dietary protein intake should be monitored. Patients should be carefully monitored to avoid over- and underhydration. An accurate fluid balance record should be kept and the patient's body weight monitored. Serum electrolyte concentrations (particularly bicarbonate, potassium, magnesium, calcium and phosphate), blood chemistry (including parathyroid hormone) and haematological parameters should be monitored periodically. Overinfusion: Overinfusion of a peritoneal dialysis solution into the peritoneal cavity may be characterised by abdominal distension/abdominal pain and/or shortness of breath. Treatment of peritoneal dialysis solution overinfusion is to drain the solution from the peritoneal cavity. Addition of Potassium: Potassium is omitted from Nutrineal solutions due to the risk of hyperkalaemia. In situations in which there is a normal serum potassium level or hypokalaemia, the addition of potassium chloride (up to a concentration of 4 mEq/L) may be indicated to prevent severe hypokalemia and should be made after careful evaluation of serum and total body potassium, only under the direction of a physician. Use in diabetic patients: In diabetic patients, blood glucose levels should be regularly monitored and the dosage of insulin or other treatment for hyperglycaemia should be adjusted. Use in patients with secondary hyperparathyroidism: In patients with secondary hyperparathyroidism, the benefits and risks of the use of dialysis solution with low calcium content should be carefully considered as it might worsen hyperparathyroidism. Paediatric population Safety and effectiveness in paediatric patients has not been established.

Pregnancy and lactation There are no clinical data on exposed pregnancies and lactation, and no animal studies are available. Nutrineal should not be used during pregnancy or lactation unless clearly necessary. See section 4.4. **Undesirable effects** The adverse reactions within this section represent those that are thought to have an association with Nutrineal or in conjunction with performing the peritoneal dialysis procedure. Undesirables effects which occurred in patients treated with Nutrineal from clinical trials and post marketing are listed below. Frequency is based upon the following scale: Very common (≥1/10); Common (≥1/100 - <1/10), Uncommon (≥1/1,000 - <1/100), Rare (≥1/10,000 - <1/1,000), Very rare (<1/10,000); not known (cannot be estimated from the available data).

Very common undesirable effects: Acidosis, Hypervolaemia, Anorexia, Vomiting, Nausea, Gastritis, Asthenia, Blood urea increased

Common undesirable effects: Infection, Anaemia, Hypokalaemia, Hypovolaemia, Depression, Abdominal pain, Dyspnoea

Not known undesirable effects: Hypersensitivity, Sclerosing encapsulating peritonitis, Abdominal discomfort, Peritonitis, Peritoneal cloudy effluent, Pruritis, Angioedema, Pyrexia, Malaise, Peritoneal fluid analysis abnormal Other undesirable effects of peritoneal dialysis related to the procedure: catheter site infection, catheter related complication, hypocalcaemia and peritonitis bacterial.

Reporting of suspected adverse reactions Reporting suspected adverse reactions after authorisation of

the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system.

For posology, incompatibilities, interactions, overdosage, pharmacological properties and pharmaceutical particulars, please refer to the full SPC.

Medicinal product subject to medical prescription
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