Baxter

Abbreviated Prescribing Information

Dianeal PD4 (Solution for peritoneal dialysis)

This abbreviated summary of product characteristics (SPC) 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

Dianeal PD4 Glucose 1.36% w/v /13.6mg/ml
Dianeal PD4 Glucose 2.27% w/v /22.7mg/ml
Dianeal PD4 Glucose 3.86% w/v /38.6mg/ml

Qualitative and quantitative composition

Dianeal PD4 Glucose 1.36% w/v /13.6mg/ml Dianeal PD4 Glucose 2.27% w/v /22.7mg/ml Dianeal PD4 Glucose 3.86% w/v /38.6mg/ml Each 1 litre contains		mmol per litre (approx.)	
Glucose Monohydrate equivalent to	15.0 or 25.0 or 42.5 g	Sodium	132
		Calcium	1.25
Anhydrous Glucose	13.6 or 22.7 or 38.6 g	Magnesium	0.25
Sodium Chloride	5.4 g	Chloride	95
Sodium Lactate	4.5 g	Lactate	40
Calcium Chloride	184 mg	mOsm per litre	344 or 395 or 483
Magnesium Chloride	51 mg		
Water for Injections to	100 % w/v		

CLINICAL PARTICULARS: Therapeutic indications Dianeal PD4 is indicated whenever peritoneal dialysis is employed, including:Acute and chronic renal failure; Severe water retention; Electrolyte disorders; Drug intoxication, when a more adequate therapeutic alternative is not available. Dianeal PD4 is particularly useful for the control of serum calcium and phosphate levels in renal failure patients receiving calcium or magnesium-containing phosphate binders. **Dosage and Route:** Intraperitoneal administration only The mode of therapy, frequency of treatment, exchange volume, duration of dwell and length of dialysis should be selected by the attending physician. Adults: Patients on continuous ambulatory peritoneal dialysis (CAPD) typically perform 4 cycles per day (24 hours). Patients on automated peritoneal dialysis (APD) typically perform 4-5 cycles at night and up to 2 cycles during the day. The fill volume depends on body size, usually from 2.0 to 2.5 litres. Paediatric population (i.e., newborn to 18 years of age): 800 to 1400 ml/m2 per cycle up to a maximum amount of 2000 ml, as tolerated, is recommended. Fill volumes of 500 to 1000 ml/m2 are recommended in children less than 2 years of age. As the patient's body weight becomes closer to the ideal dry weight, lowering the glucose concentration of DIANEAL is recommended.

Contraindications: DIANEAL is contraindicated in patients with: hypersensitivity to the active substances or to any of the excipients listed in section 6.1; pre-existing severe lactic acidosis, 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:** 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; 2) other conditions including recent aortic graft replacement and severe pulmonary disease.
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 DIANEAL PD4 as part of their PD therapy. Infrequently, fatal outcomes of EPS have been reported with DIANEAL PD4. 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. Solutions containing glucose should be used with caution in patients with a known allergy to corn or corn products. Hypersensitivity reactions such as those due to a corn starch allergy, including anaphylactic/anaphylactoid reactions, may occur. Stop the infusion immediately and drain the solution from the peritoneal cavity if any signs or symptoms of a suspected hypersensitivity reaction develop. Appropriate therapeutic countermeasures must be instituted as clinically indicated.
Patients severe lactic acidosis should not be treated with lactate-based peritoneal dialysis solutions. (See section 4.3) It is recommended that patients with conditions known to increase the risk of lactic acidosis [e.g., severe hypotension or sepsis that can be associated with acute renal failure, inborn errors of metabolism, treatment with drugs such as metformin and nucleoside/nucleotide reverse transcriptase inhibitors (NRTIs)] must be monitored for occurrence of lactic acidosis before the start of treatment and during treatment with lactate-based peritoneal dialysis solutions. When prescribing the solution to be used for an individual patient, consideration should be given to the potential interaction between the dialysis treatment and therapy directed at other existing illnesses. Serum potassium, calcium and magnesium levels should be monitored carefully in patients treated with cardiac glycosides. An accurate fluid balance record must be kept and the weight of the patient carefully monitored to avoid over- or under hydration with severe consequences including congestive heart failure, volume depletion and shock. Significant losses of protein, amino acids and water soluble vitamins may occur during peritoneal dialysis. Replacement therapy should be provided as necessary. Patients receiving low calcium solution should have their calcium levels monitored for the development of hypocalcaemia or worsening of hypercalcaemia. In these circumstances, adjustments to the dosage of the phosphate binders and/or vitamin D analogs, and/or calcimimetics should be considered by the physician. Overinfusion of DIANEAL PD4 solutions into the peritoneal cavity may be characterised by abdominal distension/abdominal pain and/or shortness of breath. Treatment of DIANEAL PD4 overinfusion is to drain the solution from the peritoneal cavity. Improper clamping or priming sequence may result in infusion of air into the peritoneal cavity, which may result in abdominal pain and/or peritonitis. Excessive use of DIANEAL PD4 peritoneal dialysis solution with a higher glucose concentration during a peritoneal dialysis treatment may result in excessive

removal of water from the patient. Potassium is omitted from DIANEAL PD4 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 hypokalaemia and should be made after careful evaluation of serum and total body potassium, only under the direction of a physician. Serum electrolyte concentrations (particularly bicarbonate, potassium, magnesium, calcium and phosphate), blood chemistry (including parathyroid hormone and lipid parameters) and haematological parameters should be monitored periodically. Diabetics require careful monitoring of blood-glucose levels during and following dialysis with glucose-containing solutions. The dosage of insulin or other treatment for hyperglycaemia should be adjusted. **Pregnancy and lactation** Pregnancy: There are no or limited amount of data from the use of DIANEAL PD4 in pregnant women. Animal studies are insufficient with respect to reproductive toxicity. DIANEAL PD4 is not recommended during pregnancy and in women of childbearing potential not using contraception. Breastfeeding It is unknown whether DIANEAL PD4 metabolites are excreted in human milk. A risk to the newborns/infants cannot be excluded. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from DIANEAL PD4 therapy taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman. Fertility There are no clinical data on fertility.
Undesirable effects *See Summary of Product Characteristics for detail.* Hypokalaemia, fluid retention, hypo-and hypervolaemia, hyponatraemia, dehydration, hypochloraemia, hypo-and hypertension, dyspnoea, sclerosing encapsulating peritonitis, peritonitis, cloudy peritoneal effluent, vomiting, diarrhoea, nausea, constipation, abdominal pain, abdominal distension, abdominal discomfort, Stevens-Johnson syndrome, urticaria, rash (including pruritic, erythematous and generalised), pruritus, myalgia, muscle spasms, musculoskeletal pain, generalised oedema, pyrexia, malaise, infusion site pain. Other undesirable effects relating to the PD procedure – fungal peritonitis, bacterial peritonitis, catheter-related infection, catheter-related complications.

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, incompabilities, side effects, warning and precautions, pharmacological properties and pharmaceutical particulars, please refer to the full SPC.

Medicinal product subject to medical prescription. Date of revision of the text: August 2016