

Baxter

Dianeal

PERITONEAL DIALYSIS SOLUTION



Currently sold in
over **75** countries
worldwide¹

Dianeal PD Solution: 40 Years of Heritage — Widely Used by Physicians

Dianeal Peritoneal Dialysis (PD) Solution is a leading treatment choice for patients receiving PD worldwide.

Dianeal Solution has a 40-year heritage and is the most widely used PD solution that Baxter produces.

- **Dianeal** (dextrose) Solution was approved in 1978^{2,a} and is currently used by more than 230,000 patients in over 75 countries.^{1,a}

Dianeal Solution provides flexibility in controlling serum calcium.

- **Dianeal** Solution is available in two concentrations of calcium in select countries.^{3,b}

Antibiotics are stable when mixed with Dianeal Solution, offering patients added convenience.

- In an in vitro^c study, bioassays showed that antibiotics (cefepime, cefazolin and ampicillin) made up in **Dianeal** (2.5% glucose) Solution were stable and demonstrated bioactivity after being stored for three weeks at 4 °C or for nine days at 25 °C.^{4,d}
- Vancomycin is stable when mixed with **Dianeal** Solution,^{5,d,e} and can be used to treat Gram-positive infections, as recommended by ISPD guidelines.^{6,f}

HPLC, high-performance liquid chromatography; ISPD, International Society for Peritoneal Dialysis; PD, peritoneal dialysis.

^aApproval in the US. Correct as of July 2018. ^bPatients receiving low-calcium **Dianeal** Solutions should have their calcium levels monitored for the development of hypocalcemia or worsening of hypercalcemia. 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.³ ^cIn vitro data may not translate into clinical outcomes. ^dAdditional combinations of medications and Baxter PD solutions were also assessed. See study for further details.⁵ ^eVancomycin concentration was >99% of the initial value when stored for 24 hours at 25 °C.⁵ ^fIn an in vitro^c study, HPLC analysis showed that vancomycin made up in **Dianeal** Solution was stable for 24 hours at 25 °C and for an additional 4 hours at 37 °C.⁵

Dianeal PD4 [solution for peritoneal dialysis]^{3,7}

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, 25.0 or 42.5 g	Sodium—132
Anhydrous Glucose—13.6, 22.7 or 38.6 g	Calcium—1.25
Sodium Chloride—5.4 g	Magnesium—0.25
Sodium Lactate—4.5 g	Chloride—95
Calcium Chloride—184 mg	Lactate—40
Magnesium Chloride—51 mg	mOsm per litre—344 or 395 or 483
Water for Injections to—100 % w/v	

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 ileostomy, 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, hypochloroemia, 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, incompatibilities, 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

³ See the full prescribing information of each solution for further details.

References:

1. Baxter. Data on file. Patient counts for Baxter PD solutions. 2018.
2. FDA. Dianeal product monograph. 1978.
3. Baxter. Dianeal Solution SmPC. August 2016.
4. Roberts DM, Fernando G, Singer RF, et al. Antibiotic stability in commercial peritoneal dialysis solutions: influence of formulation, storage and duration. *Nephrol Dial Transplant*. 2011 Oct;26(10):3344-3349.
5. Voges M, Faict D, Lechien G, Taminne M. Stability of drug additives in peritoneal dialysis solutions in a new container. *Perit Dial Int*. 2004 Nov-Dec;24(6):590-595.
6. Li PK, Szeto CC, Piraino B, et al. ISPD Peritonitis Recommendations: 2016 Update on Prevention and Treatment. *Perit Dial Int*. 2016 Sep 10;36(5):481-508.
7. FDA. Dianeal label. 2015. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/020183s024tbl.pdf Accessed February 1, 2019.

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