

**Baxter**

**Dianeal**

PERITONEAL DIALYSIS SOLUTION



Currently sold in  
over **75** countries  
worldwide<sup>1</sup>

# 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 nearly 40-year heritage and is the most widely used PD solution that Baxter produces.

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

**Dianeal** Solution provides flexibility in controlling serum calcium.

- **Dianeal** Solution is available in two concentrations of calcium in select countries.<sup>3,b</sup>

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

- In an in vitro<sup>c</sup> 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.<sup>4,d</sup>
- Vancomycin is stable when mixed with **Dianeal** Solution,<sup>5,d,e</sup> and can be used to treat Gram-positive infections, as recommended by the ISPD guidelines.<sup>6,f</sup>

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

<sup>a</sup>Approval in the US. Correct as of July 2018. <sup>b</sup>Patients 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.<sup>3</sup> <sup>c</sup>In vitro data may not translate into clinical outcomes. <sup>d</sup>Additional combinations of medications and Baxter PD solutions were also assessed. See study for further details.<sup>5</sup> <sup>e</sup>Vancomycin concentration was >99% of the initial value when stored for 24 hours at 25 °C.<sup>5</sup> <sup>f</sup>In an in vitro<sup>c</sup> 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.<sup>5</sup>

# Dianeal Peritoneal Dialysis Solutions

## MINIMUM PRODUCT INFORMATION

Please see full Product Information before prescribing.

## NAME OF MEDICINE

Dianeal® PD-2, PD-4 and 1mmol/L Calcium Peritoneal Dialysis Solutions.

## DESCRIPTION

Dianeal® PD-2, PD-4 and 1mmol/L Calcium Peritoneal Dialysis Solutions are sterile, nonpyrogenic and contain no bacteriostatic or antimicrobial agents or added buffers.

Each 1000 mL of Dianeal® Peritoneal Dialysis Solution contains:

Component	Content
Glucose, BP	0.55% - 5.5 g,
	1.5 % - 15.0 g,
	2.5 % - 25.0 g, or
	4.25% - 42.5 g
Sodium Chloride, BP	5.38 g
Sodium Lactate	4.48 g
Magnesium Chloride Hexahydrate, BP	50.8 g
Calcium Chloride Dihydrate, BP	PD-2 257 mg,
	PD-4 183 mg, or
	1mmol/L Calcium 147 mg
Water for Injections, BP	QS

## INDICATIONS

Dianeal® PD-2, PD-4 and 1mmol/L Calcium Peritoneal Dialysis Solution is indicated for use in chronic renal failure patients being maintained on Continuous Ambulatory Peritoneal Dialysis.

## CONTRAINDICATIONS

DIANEAL is contraindicated in patients with pre-existing severe lactic acidosis. Do not administer unless the solution is clear and the seal is intact.

## PRECAUTIONS

Peritoneal dialysis should be done with great care, if at all, in patients with (1) a number of abdominal conditions including disruption of the peritoneal membrane or diaphragm by surgery, from congenital anomalies or trauma until healing is complete, abdominal tumours, extensive adhesions, bowel distension, undiagnosed abdominal disease, abdominal wall infection, hernias or burns, faecal fistula or colostomy, tense ascites, obesity, and 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 replacement and severe pulmonary disease. When assessing peritoneal dialysis as the mode of therapy in such extreme situations, the benefits to the patient must be weighed against the possible complications.

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 DIANEAL. Infrequently, fatal outcomes of EPS have been reported with DIANEAL.

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.

See full product Information for

*Use in Pregnancy (Category B2)*

There are no adequate data from the use of DIANEAL in pregnant women. Physicians should carefully consider the potential risks and benefits for each specific patient before prescribing DIANEAL.

## ADVERSE EFFECTS

Adverse reactions to peritoneal dialysis include mechanical and solution related problems as well as the results of contamination of equipment or improper technique in catheter placement. Abdominal pain, bleeding, peritonitis, subcutaneous infection around a chronic peritoneal catheter, catheter blockage, difficulty in fluid removal, and ileus are among the complications of the procedure. Solution related adverse reactions may include electrolyte and fluid imbalances, hypovolaemia, hypervolaemia, hypertension, hypotension, and muscle cramping and hyperphosphatemia [which may induce secondary hyperparathyroidism].

Please refer to full product Information for 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/2015/020183s024lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/020183s024lbl.pdf) Accessed February 1, 2019.

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## DOSAGE AND ADMINISTRATION

Dianeal® PD-2, PD-4 and 1mmol/L Calcium Solutions are intended for intraperitoneal administration only. They are not for Intravenous administration. The mode of therapy (Continuous Ambulatory Peritoneal Dialysis), frequency of treatment, formulation, exchange volume, duration of dwell, and length of dialysis should be selected by the physician responsible for and supervising the treatment of the individual patient.

To avoid the risk of severe dehydration and hypovolaemia and to minimise the loss of protein, it is advisable to select the peritoneal dialysis solution with the lowest level of osmolality consistent with the fluid removal requirements for that exchange.

Heating the dialysis solution to 37°C may decrease discomfort and heat loss and result in increased clearances of urea when compared to solution at room temperature (Gross and McDonald 1967). However, only dry heat (eg heating pad, warming plate) should be used. Solutions should not be heated in water or in a microwave oven. The addition of heparin to the dialysis solution may be indicated to aid in prevention of catheter blockage in patients with peritonitis, or when the solution drainage contains fibrinous or proteinaceous material (Ribot et al. 1966). 1000 to 2000 International Units of heparin per litre of solution has been recommended (Furman et al. 1978).

Aseptic technique should be employed throughout the peritoneal dialysis procedure.

Do not administer if the solution is discoloured, cloudy, contains particulate matter or shows evidence of leakage, or if seals are not intact.

The drained fluid should be inspected for the presence of fibrin or cloudiness, which may indicate the presence of peritonitis.

Discard any unused solution.

For single use only.

## CONTINUOUS AMBULATORY PERITONEAL DIALYSIS (CAPD)

For maintenance dialysis of chronic renal failure patients.

In this technique, typically 1.5 to 2.0 litres of dialysis solution (depending upon patient size) are instilled into the peritoneal cavity and the peritoneal access device is then clamped. The solution remains in the cavity for dwell times of 4 - 6 hours during the day and approximately eight hours overnight. At the conclusion of each dwell period, the access device is opened, the solution drained and fresh solution instilled. The procedure is repeated 3 - 5 times per day, 6 -7 days per week. Typically, the majority of exchanges will utilise 1.5% and 2.5% Glucose containing peritoneal dialysis solutions, with 4.25% Glucose containing solutions being used when extra fluid removal is required. Patient weight is used as the indicator of the need for fluid removal (Popovich et al. 1978).

## DIRECTIONS FOR USE

Use aseptic technique. To add medication:

1. Prepare medication site. If the resealable rubber plug on the medication port is missing or partially removed, do not use product if medication is to be added.
2. Using syringe with 19 - 22 gauge needle, puncture resealable rubber plug at target area and inject.
3. Mix solution and medication thoroughly. For high density medication such as potassium chloride, squeeze medication port while port is upright and mix thoroughly.

Preparation for Administration

1. Place container on table or suspend from support.
2. Remove protector from outlet port of container.
3. Attach solution transfer set; refer to complete directions accompanying set.

## NAME AND ADDRESS OF SPONSOR

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