NEW ZEALAND DATA SHEET

1. DIANEAL Peritoneal Dialysis Solutions

Dianeal PD4 with 1.5% w/v glucose monohydrate Dialysis solution

Dianeal PD4 with 2.5% w/v glucose monohydrate Dialysis solution

Dianeal PD4 with 4.25% w/v glucose monohydrate Dialysis solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

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

The compositions of the DIANEAL Peritoneal Dialysis (PD) Solutions are provided in:

- Table 1 - Ingredient concentration (mg/L or g/L) and
- Table 2 – Ingredient concentration (mmol/L) and Osmolarity

Table 1: DIANEAL PD solution - Ingredient concentration (mg/L or g/L)

Ingredients	DIANEAL 1 mmol/L Calcium				DIANEAL PD-4				DIANEAL PD-2			
	with Glucose monohydrate				with Glucose monohydrate				with Glucose monohydrate			
	0.55%	1.5%	2.5%	4.25%	0.55%	1.5%	2.5%	4.25%	0.55%	1.5%	2.5%	4.25%
Glucose monohydrate (g/L)	5.5	15	25	42.5	5.5	15	25	42.5	5.5	15	25	42.5
Sodium Chloride (g/L)	5.38				5.38				5.38			
Sodium Lactate (g/L)	4.48				4.48				4.48			
Magnesium Chloride Hexahydrate (mg/L)	50.8				50.8				50.8			
Calcium Chloride Dihydrate (mg/L)	147				183				257			
Water for Injections	QS				QS				QS			

Table 2: DIANEAL PD solution - Ingredient concentration (mmol/L) and Osmolarity

	DIANEAL 1 mmol/L Calcium				DIANEAL PD-4				DIANEAL PD-2			
	with Glucose monohydrate				with Glucose monohydrate				with Glucose monohydrate			
	0.55%	1.5%	2.5%	4.25%	0.55%	1.5%	2.5%	4.25%	0.55%	1.5%	2.5%	4.25%
Glucose (mmol/L)	28	76	126	214	28	76	126	214	28	76	126	214
Sodium (mmol/L)	132				132				132			
Magnesium (mmol/L)	0.25				0.25				0.25			
Calcium (mmol/L)	1				1.25				1.75			
Chloride (mmol/L)	95				95				96			
Lactate (mmol/L)	40				40				40			
Approximate Osmolarity (mOsmol/L)	296	344	394	482	297	345	395	483	298	346	396	485

Potassium is omitted from DIANEAL Solutions because dialysis may be performed to correct hyperkalaemia.

Because average plasma magnesium levels in chronic Continuous Ambulatory Peritoneal Dialysis (CAPD) patients have been observed to be elevated[1], the magnesium concentration of this formulation has been reduced to 0.25 mmol/L.

Because average serum bicarbonate levels in chronic CAPD patients have been observed to be somewhat lower than normal values[1], the bicarbonate precursor (lactate) concentration of this formulation has been raised to 40 mmol/L.

DIANEAL Solutions Freeline Solo Twin Bag

The solution contained in the Freeline Solo Products can be DIANEAL PD-2, PD-4 or 1 mmol/L Calcium. The solution bag is attached to a Y set and an empty container. Freeline Solo is a completely disposable exchange package. A fresh sterile pack is used for each exchange and this system requires only one connection per exchange.

3. PHARMACEUTICAL FORM

Clear, slightly coloured peritoneal dialysis solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

DIANEAL Peritoneal Dialysis Solution is indicated for use in chronic renal failure patients being maintained on CAPD.

4.2 Dose and method of administration

DIANEAL PD-2, PD-4 and 1 mmol/L Calcium Solutions are intended for intraperitoneal administration only. The mode of therapy CAPD, 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 osmolarity consistent with the fluid removal requirements for that exchange.

As the patient's body weight becomes closer to the ideal dry weight, lowering the glucose concentration of DIANEAL Solution is recommended. DIANEAL 4.25% glucose solution is a high osmotic pressure fluid and using it alone may cause dehydration (see section 4.4 Special Warnings and Precautions for use).

Heating the dialysis solution to 37°C (while in the overpouch) may decrease discomfort and heat loss and result in increased clearances of urea when compared to solution at room temperature[2]. Only dry heat (eg. heating pad, warming plate) should be used; solutions should not be heated in water or in a microwave oven due to the potential for patient injury or discomfort.

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[3]. 1000 to 2000 International Units of heparin per litre of solution has been recommended[4].

Continuous Ambulatory Peritoneal Dialysis (CAPD):

For maintenance dialysis of chronic renal failure patients.

In this technique, typically 1.5 to 2litres 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 DIANEAL 1.5% and 2.5% glucose solutions, with DIANEAL 4.25% Glucose solutions being used when extra fluid removal is required. Patient weight is used as the indicator of the need for fluid removal[5].

Directions for Use:

DIANEAL Solutions are intended for intraperitoneal administration only. Do not use for intravenous administration. Do not administer if the solution is discoloured, cloudy, contains particulate matter or shows evidence of leakage or if seals are not intact.

Use aseptic technique throughout the peritoneal dialysis procedure. 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.

The drained fluid should be inspected for the presence of fibrin or cloudiness, which may indicate the presence of peritonitis. Discard any unused remaining solution. Use in one patient in one occasion only.

4.3 Contraindications

Do not administer unless the solution is clear and the seal is intact.

DIANEAL Solutions are contraindicated in patients with:

- pre-existing severe lactic acidosis;
- uncorrectable mechanical defects that prevent effective peritoneal dialysis or increase the risk of infection;
- documented loss of peritoneal function or extensive adhesions that compromise peritoneal function.

4.4 Special warnings and precautions for use

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 Solutions.

Improper clamping or priming sequence may result in infusion of air into the peritoneal cavity, which may result in abdominal pain and/or 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.

Solutions containing dextrose 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 with severe lactic acidosis should not be treated with lactate-based peritoneal dialysis solutions (see section 4.3 Contraindications). 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.

Azotaemic diabetics require careful monitoring of insulin requirements during and following dialysis with glucose-containing solutions. DIANEAL Solutions contain varying concentrations of glucose monohydrate, ranging between 0.55 to 4.25%. In diabetic patients, blood glucose levels should be

regularly monitored, and the dosage of insulin or other treatments for hyperglycaemia should be adjusted.

Aseptic technique must be used throughout the procedure and at its termination in order to reduce the possibility of infection. 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.

Peritoneal dialysis should be done with great care, if at all, in patients with a number of abdominal conditions including disruption of the peritoneal membrane and diaphragm by surgery or 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, colostomy or ileostomy, frequent episodes of diverticulitis, inflammatory or ischaemic bowel disease, tense ascites, obesity, and large polycystic kidneys, or other conditions that compromise the integrity of the abdominal wall, abdominal surface, or intra-abdominal cavity. Peritoneal dialysis should also be done with caution in patients with 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.

Protein, amino acids, water-soluble vitamins, and other medicines may be lost during peritoneal dialysis and may require replacement.

Patients should be carefully monitored to avoid over- and under-hydration. An accurate fluid balance record must be kept and the weight of the patient carefully monitored to avoid over- or under-hydration and severe consequences including congestive heart failure, volume depletion, and shock. Excessive use of DIANEAL PD-2, PD-4 and 1 mmol/L Calcium Solutions with 4.25% glucose monohydrate during peritoneal dialysis treatment can result in significant removal of water from the patient. Over-infusion of a DIANEAL volume into the peritoneal cavity may be characterised by abdominal distension, abdominal pain and/or shortness of breath (for treatment of over-infusion see section 4.9 Overdose).

Routine periodic evaluation of blood chemistries (including parathyroid hormone and lipid parameters), serum electrolyte concentrations (particularly bicarbonate, potassium, magnesium, calcium and phosphate) and haematologic factors, as well as other indicators of patient status, should be performed for stable patients undergoing maintenance peritoneal dialysis.
Potassium is omitted from DIANEAL PD-2, PD-4 and 1 mmol/L Calcium Solutions because dialysis may be performed to correct hyperkalaemia. In situations where there is normal serum potassium or hypokalaemia, addition of potassium chloride (up to 4 meq/l) to prevent severe hypokalaemia should be made after careful evaluation of serum and total body potassium and only under the direction of a physician.

Not for use in the treatment of lactic acidosis.

Low Calcium DIANEAL PD solution should be considered with patients with hypercalcaemia. Patients receiving this 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 should be considered by the physician.

Hyperphosphataemia may develop from use of DIANEAL 1 mmol/L Calcium Solutions which may subsequently lead to secondary hyperparathyroidism. Dialysis using DIANEAL 1 mmol/L Calcium Solution requires close and continuous monitoring of PTH and bone metabolism.

Because average plasma magnesium levels in chronic CAPD patients have been observed to be elevated[1] , the magnesium concentration of this formulation has been reduced to 0.25 mmol/L. Serum magnesium levels should be monitored and if low, oral magnesium supplements, oral magnesium containing phosphate binders, or peritoneal dialysis solutions containing higher magnesium concentrations may be used.

Use in the elderly
No data available.

Paediatric use
No data available.

Effects on laboratory tests
No data available.

4.5 Interaction with other medicines and other forms of interaction

No clinical drug interaction studies have been conducted with DIANEAL Solutions.

Significant losses of protein, amino acids and water-soluble vitamins, as well as other dialysable medicines may occur during peritoneal dialysis. Replacement therapy should be provided as necessary.

See section 6.2 Incompatibilities.

4.6 Fertility, pregnancy and lactation

Effects on fertility
No data available.

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

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

4.7 Effects on ability to drive and use machines

The effects of this medicine on a person's ability to drive and use machines were not assessed as part of its registration.

4.8 Undesirable 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 Hyperphosphataemia (which may induce secondary hyperparathyroidism).

The following adverse reactions have been reported in post-marketing experience:

INFECTIONS AND INFESTATIONS: Fungal peritonitis, bacterial peritonitis, catheter- related infection.

METABOLISM AND NUTRITION DISORDERS: Hypovolaemia, hypervolaemia, fluid retention, hypokalaemia, hyponatraemia, dehydration and hypochloraemia.

VASCULAR DISORDERS: Hypotension and hypertension.

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS: Dyspnoea.

GASTROINTESTINAL DISORDERS: Sclerosing Encapsulating Peritonitis, peritonitis, peritoneal cloudy effluent, vomiting, diarrhoea, nausea, constipation, abdominal pain, abdominal distension, abdominal discomfort.

SKIN AND SUBCUTANEOUS DISORDERS: Stevens-Johnson syndrome, urticaria, rash (including pruritic, erythematous and generalised) and Pruritus.

MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS: Myalgia, muscle spasms and musculoskeletal pain.

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS: generalised oedema, pyrexia, malaise, infusion site pain and catheter-related complication.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions https://pophealth.my.site.com/carmreportnz/s/

4.9 Overdose

Overdose by over infusion of a DIANEAL Solutions into the peritoneal cavity is characterised by abdominal pain and distension and shortness of breath.

There is a potential for overdose resulting in hypervolaemia, hypovolaemia, electrolyte disturbances or hyperglycaemia. Excessive use of DIANEAL peritoneal dialysis solution with 4.25% glucose monohydrate during a peritoneal dialysis treatment can result in significant removal of water from the patient.

Treatment of DIANEAL Solutions overdose by over infusion is to release the DIANEAL Solution from the peritoneal cavity by drainage of the DIANEAL Solution volume contained within the peritoneal cavity. Hypovolaemia may be managed by fluid replacement either orally or intravenously, depending on the degree of dehydration.

Electrolyte disturbances may be managed according to the specific electrolyte disturbance verified by blood testing. The most probable disturbance, hypokalaemia, may be managed by the oral ingestion of potassium or by the addition of potassium chloride in the peritoneal dialysis solution prescribed by the treating physician. Hyperglycaemia in diabetic patients may be managed by adjusting the insulin dose or oral medications.

For risk assessment and advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Mechanism of action

Peritoneal dialysis is a procedure for removing toxic substances and metabolites normally excreted by the kidneys, and for aiding in the regulation of fluid and electrolyte balance.

The procedure is accomplished by instilling peritoneal dialysis fluid through a conduit into the peritoneal cavity. With the exception of lactate, present as a bicarbonate precursor, electrolyte concentrations in the fluid have been formulated in an attempt to normalise plasma electrolyte concentrations which are controlled by osmosis and diffusion across the peritoneal membrane (between the plasma of the patient and the dialysis fluid). Toxic substances and metabolites, present in high concentration in the blood, cross the peritoneal membrane into the dialysing fluid. Glucose in the dialysing fluid is used to produce a solution hyperosmolar to the plasma, creating an osmotic gradient which facilitates transfer of extracellular fluid into the peritoneal cavity. After a period of time (dwell time), the fluid is drained by gravity from the cavity.

Clinical trials

No data available.

5.2 Pharmacokinetic properties

No data available.

5.3 Preclinical safety data

Genotoxicity

No data available.

Carcinogenicity

No data available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for Injections.

6.2 Incompatibilities

Additives may be incompatible. Consult with pharmacist familiar with peritoneal dialysis, if available. When introducing additives, refer to directions for use accompanying drugs to obtain full information on additives, and use aseptic techniques. Mix thoroughly. Do not store.

Refer to manufacturer's directions accompanying drugs to obtain full information on additives.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Store below 30°C. Do not administer unless the solution is clear and the bag undamaged.

6.5 Nature and contents of container

DIANEAL Solutions are available in the following fill volumes and configurations:

Table 3: Dianeal Solutions fill volume and configurations*

	DIANEAL 1 mmol/L Calcium with 0.55%, 1.5%, 2.5% or 4.25% Glucose monohydrate	DIANEAL PD-4 with 0.55%, 1.5%, 2.5% or 4.25% Glucose monohydrate	DIANEAL PD-2 with 0.55%, 1.5%, 2.5% or 4.25% Glucose monohydrate
Single Bag	2000 mL (in 2 L bag) 2500 mL (in 3 L bag) 3000 mL (in 3 L bag) 5000 mL (in 5 L bag) 6000 mL (in 5 L bag)	1000 mL (in 1 L bag) 1500 mL (in 2 L bag) 2000 mL (in 2 L bag) 2500 mL (in 3 L bag) 3000 mL (in 3 L bag) 5000 mL (in 5 L bag) 6000 mL (in 5 L bag)	500 mL (in 1 L bag) 1000 mL (in 1 L bag) 1500 mL (in 2 L bag) 2000 mL (in 2 L bag) 2500 mL (in 3 L bag) 3000 mL (in 3 L bag) 5000 mL (in 5 L bag) 6000 mL (in 5 L bag)
Twin Bag	1500 mL (in 2 L bag) 2000 mL (in 2 L bag) 2500 mL (in 3 L bag) 3000 mL (in 3 L bag)	1500 mL (in 2 L bag) 2000 mL (in 2 L bag) 2500 mL (in 3 L bag) 3000 mL (in 3 L bag)	1500 mL (in 2 L bag) 2000 mL (in 2 L bag) 2500 mL (in 3 L bag) 3000 mL (in 3 L bag)

*Not all pack sizes are marketed.

6.6 Special precautions for disposal

Any unused product or waste material should be disposed of in accordance with local requirements.

7. MEDICINE SCHEDULE

General Sale Medicine.

8. SPONSOR

DIANEAL PD Solutions is distributed in New Zealand by:
Vantive Ltd
33 Vestey Drive
Mt Wellington
Auckland 1060
Phone0800 436 770.

DIANEAL PD Solutions is distributed in Australia by:
VANTIVE Pty Ltd
Suite 30.1 155 Miller Street
North Sydney NSW 2060
AUSTRALIA

9. DATE OF FIRST APPROVAL

Date of publication in the New Zealand Gazette of consent to distribute the medicine:
24 February 2011

10. DATE OF REVISION OF THE TEXT

31 August 2026

SUMMARY TABLE OF CHANGES

Section changed	Summary of new information
All	First version of the data sheet

References

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2. Gross, M. and McDonald, Jr., H.P. 1967. Effect of dialysate temperature and flow rate on peritoneal clearance. JAMA 202: 363 – 365.
3. Ribot, S. et al. 1966. Complications of peritoneal dialysis. AM J. Med Sciences 252: 505 –517.
4. Furman, K.I. et al. 1978. Activity of intraperitoneal heparin during peritoneal dialysis. Clin Nephrol 9: 15 – 18.
5. Popovich, R.P. et al. 1978. Continuous ambulatory peritoneal dialysis. Annals Intern Med 8: 449 – 456.