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DIANEAL PD4			
	Glucose 1.36% w/v	Glucose 2.27% w/v	Glucose 3.86% w/v
Formula per 1000 ml	g/l	g/l	g/l
Glucose Monohydrate equivalent to Anhydrous Glucose $C_6H_{12}O_6$	13.6	22.7	38.6
Sodium Chloride $NaCl$	5.4	5.4	5.4
Sodium Lactate $C_3H_5NaO_3$	4.5	4.5	4.5
Calcium Chloride $CaCl_2 \cdot 2H_2O$	0.184	0.184	0.184
Magnesium Chloride $MgCl_2 \cdot 6H_2O$	0.051	0.051	0.051
Water for Injections (ml)	1000	1000	1000
	mmol/l	mmol/l	mmol/l
Sodium Na^+	132	132	132
Lactate $C_3H_5O_3^-$	40	40	40
Calcium Ca^{++}	1.25	1.25	1.25
Magnesium Mg^{++}	0.25	0.25	0.25
Chloride Cl^-	95	95	95
mOsm/l	344	395	483
pH	5.5	5.5	5.5

Holder of marketing authorisation:

Baxter Healthcare S.A., Castlebar, Co. Mayo, Ireland.

Product may be manufactured by:

Baxter Healthcare Ltd., GB-Thetford, Norfolk, IP24 3SE.

Baxter S.A., Sesto, Fiorentino, Italy.

NV Baxter, Lessines, Belgium.

Baxter S.L., Valencia, Spain.

Baxter Healthcare S.A., Castlebar, Co. Mayo, Ireland.

What is DIANEAL PD4?

It is a peritoneal dialysis solution contained in plastic bags. The solution is available in 3 different strengths of glucose, that is, 1.36, 2.27 and 3.86% w/v. Each of the three strengths are available in different volumes, (litres): 0.25, 0.5, 0.75, 1, 1.5, 2, 2.5, 3 and 5.

What is DIANEAL PD4 used for?

The solution is used in patients whose kidneys are either temporarily or permanently not working. It removes water and waste products from the blood and corrects abnormal blood levels of salt. The higher strength of glucose in the solution, the greater the amount of water that can be removed from the blood.

This solution is indicated whenever peritoneal dialysis is employed, including: acute and chronic renal failure; severe water retention; electrolyte disorders; and drug intoxication, when a more adequate therapeutic alternative is not available.

This solution is for intraperitoneal administration only.

When must DIANEAL PD4 not be used?

When assessing whether peritoneal dialysis is a suitable type of treatment for you, your doctor will have taken into account any factors in your medical history which might exclude the use of peritoneal dialysis solutions.

Some clinical conditions such as recent abdominal surgery and certain gastrointestinal disorders have to be considered as contraindications. In each case the benefits of treatment must be weighed against the possible complications.

When using peritoneal dialysis as a form of therapy during advanced pregnancy, the doctor will assess the benefits of this treatment to you against the possible complications.

What precautions should be taken using DIANEAL PD4?

- Your doctor will advise you about particular precautions as they apply to you. In acute renal failure patients, plasma electrolyte concentrations should be monitored periodically during the procedure. In chronic treatment, blood chemistry and haematological factors as well as other indicators of patient status should be periodically evaluated. It is advisable to monitor serum calcium and phosphate levels in patients on this therapy. Significant losses of protein, amino acids and water soluble vitamins may occur during peritoneal dialysis. Replacement therapy should be provided as necessary.

- Keep a written note of your weight, fluid balance and any other measurements which your doctor has asked you to record. 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.

- Contact your doctor if your drain volume is more than expected. Excessive use of DIANEAL PD4 3.86 during a peritoneal dialysis treatment can result in significant removal of water.

- Aseptic technique should be observed throughout the bag change procedure.

Can other medicines interfere with the actions of DIANEAL PD4?

Before you take any other medicine in addition to DIANEAL PD4 talk to your doctor. The doctor will check compatibilities of the solution with any additives he uses. No interactions are known.

What is the usual dosage of DIANEAL PD4?

The solution is for intraperitoneal administration only by way of a catheter into the abdomen. It is important to take your solutions as directed by your doctor. He will have told you which strengths of glucose and which volumes of solution you must use, as well as how often each day you must change bags.

What are the possible undesirable effects of peritoneal dialysis?

Peritoneal dialysis may cause some undesirable effects in addition to its beneficial effects. Contact your doctor if you experience any of the following or if you notice any other effects:

- High temperature, feeling sick, stomach pain or shivering/flu-like symptoms.
- Redness, pus, swelling or pain around the exit site of your catheter.
- Rapid weight increase, swollen ankles or legs, puffy eyes, rise in blood pressure, shortness of breath or chest pain.
- Weight loss, fall in blood pressure, feeling light headed or dizzy, muscle cramp or thirst.
- Constipation.

Undesirable effects include procedure and solution related problems. Those which are related to the procedure are abdominal pain, bleeding, peritonitis, infection around the catheter, catheter blockage and ileus. Those which are related to peritoneal dialysis solutions include electrolyte and fluid imbalances, hypo- and hypervolaemia, hypo- and hypertension, muscle cramping and dysequilibrium syndrome.

Further important information

- Do not use the solution after the expiry date printed on the bag.
- Do not use the solution unless it is clear and the bag is intact.
- Store your bags at or below 25°C and away from excessive cold.
- The solution should be kept out of the reach of children.

This leaflet was last revised in June 2005.