SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Dianeal PD1 Glucose 3.86% w/v 38.6 mg/ml

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

	Anhydrous Glucose	Ph.Eur.	3.86% w/v
or	Glucose Monohydrate	Ph.Eur.	
	Sodium Chloride	Ph.Eur.	0.57% w/v
	Sodium Lactate	Ph.Fr.	0.39% w/v
	Calcium Chloride	Ph.Eur.	0.0257% w/v
	Magnesium Chloride	Ph.Eur.	0.0152% w/v

3. PHARMACEUTICAL FORM

Solution for peritoneal dialysis.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Dianeal PD1 is indicated whenever peritoneal dialysis is employed, including:

1. Acute and chronic renal failure;
2. Severe water retention;
3. Electrolyte disorders;
4. Drug intoxication, when a more adequate therapeutic alternative is not available.

Route of administration

Intraperitoneal administration only.

4.2. Posology and method of administration

The mode of therapy, frequency of treatment, exchange volume, duration of dwell and length of dialysis should be selected by the attending physician.

As an average, 3 to 5 exchanges per day using 1500ml to 3000ml solution are recommended.

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

For children, individual dialysis prescription is necessary, which includes appropriate adaptation of fill volumes.

4.3. Contraindications

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

4.4. SPECIAL WARNINGS AND SPECIAL PRECAUTIONS FOR USE

i) An accurate fluid balance record must be kept and the weight of the patient carefully monitored to avoid over- or underhydration with severe consequences including congestive heart failure, volume depletion and shock.

ii) Excessive use of Dianeal PD1 3.86 during a peritoneal dialysis treatment can result in significant removal of water.

iii) 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.

iv) It is advisable to monitor serum calcium and phosphate levels in patients on this therapy.

v) Significant losses of protein, amino acids and water soluble vitamins may occur during peritoneal dialysis. Replacement therapy should be provided as necessary.

vi) Aseptic technique should be observed throughout the bag change procedure.

vii) Hypokalaemia should be corrected prior to instilling Dianeal treatment, or by addition of potassium to the Dianeal solution.

viii) Serum potassium levels should be monitored carefully in patients treated with cardiac glycosides.

ix) In diabetic patients blood glucose levels should be regularly monitored, and the dosage of insulin or other treatment for hyperglycemia should be adjusted.

x) In case of peritonitis, appropriate treatment should be undertaken by the physician.

xi) Label warnings
- Do not use unless solution is clear
- Discard unused solution
- Not for Intravenous Infusion
- For Intraperitoneal infusion

4.5. Interaction with other medicaments and other forms of interaction

Medication which are either removed by the dialysis procedure or metabolised by the kidney may need to be adjusted.

4.6. Pregnancy and lactation

When assessing peritoneal dialysis as a mode of therapy during advanced pregnancy, the benefits to the patient must be weighed against the possible complications.

4.7. EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

Not appropriate.

4.8. Undesirable effects

Undesirable effects of peritoneal dialysis 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.

4.9. Overdose

Not appropriate.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

For patients with renal failure, peritoneal dialysis is a procedure for removing toxic substances produced by nitrogen metabolism and normally excreted by the kidneys, and for aiding the regulation of fluid and electrolyte as well as acid base balances.

This procedure is accomplished by administering peritoneal dialysis fluid through a catheter into the peritoneal cavity. Transfer of substances between the dialysis fluid and the patient's peritoneal capillaries is made across the peritoneal membrane according to the principles of osmosis and diffusion. After a few hours of dwell time, the solution is saturated with toxic substances and must be changed. 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. Nitrogenous waste products, present in high concentration in the blood, cross the peritoneal membrane into the dialysing fluid. Glucose produces a solution hyperosmolar to the plasma, creating an osmotic gradient which facilitates fluid removal from the plasma to the solution, necessary to compensate for the overhydration observed in chronic renal failure patients.

5.2. Pharmacokinetic properties

Intraperitoneally administered glucose is absorbed into the blood and metabolised by the usual pathways.

5.3. Preclinical safety data

Not appropriate.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Water for Injections to 100% w/v

6.2. Incompatibilities

Compatibilities should be checked when additives are used.

Admixed solutions should be used immediately.

6.3. Shelf life

The shelf life of the product as packaged for sale is 24 months. The product, once removed from its overpouch, should be used immediately.

6.4. Special precautions for storage

The product should be stored at or below 25°C.

6.5. Nature and content of container

The fluid is hermetically sealed inside a bag manufactured from medical grade plasticised PVC, designated PL-146. The bag is fitted with a port for connection to a suitable administration set, or alternatively the bag may be connected to an integral administration set and empty drainage bag. The bag is also fitted with a resealable latex injection port for the addition of medication to the solution prior to administration, if appropriate.

The bag is then sealed inside an overpouch manufactured from high density polyethylene or polypropylene.

Container sizes: 250ml, 500ml, 750ml, 1000ml, 1500ml, 2000ml, 2500ml, 3000ml and 5000ml.

6.6. Instructions for use/handling

Detailed instruction on the CAPD exchange procedures is given to patients by means of specialised training, and in the leaflet.

7. MARKETING AUTHORISATION HOLDER

Baxter Healthcare Ltd.,
Caxton Way,
Thetford,
Norfolk,
IP24 3SE,
UK

8. MARKETING AUTHORISATION NUMBER

PL 00116/0079

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

First Authorisation Date: 14.01.80
Renewal of the Authorisation: 30.09.04

10. DATE OF REVISION OF THE TEXT

September 2001.