

PACKAGE LEAFLET: INFORMATION FOR THE USER

DIANEAL PD4 Glucose 1.36% w/v / 13.6 mg/ml

DIANEAL PD4 Glucose 2.27% w/v / 22.7 mg/ml

DIANEAL PD4 Glucose 3.86% w/v / 38.6 mg/ml

Solutions for Peritoneal Dialysis

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- If you get any side effects talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What DIANEAL PD4 is and what it is used for
2. What you need to know before you use DIANEAL PD4
3. How to use DIANEAL PD4
4. Possible side effects
5. How to store DIANEAL PD4
6. Contents of the pack and other information

1. What DIANEAL PD4 is and what it is used for

DIANEAL PD4 is a solution for peritoneal dialysis.

It removes water and waste products from the blood. It also corrects abnormal levels of different blood components. DIANEAL PD4 contains varying levels of glucose (1.36%, 2.27% or 3.86%). The higher the strength of glucose in the solution, the greater the amount of water that will be removed from the blood.

DIANEAL PD4 may be prescribed to you if you have:

- either temporary or permanent kidney failure
- severe water retention
- severe disturbances in the acidity or alkalinity and the level of salts in your blood
- certain types of drug intoxication where no other treatments are available.

DIANEAL PD4 is particularly indicated for the control of your serum calcium and phosphate levels if you receive calcium or magnesium containing phosphate binders.

2. What you need to know before you use DIANEAL PD4

Do not use DIANEAL PD4

- If you are allergic to active substances or any of the other ingredients of this medicine (listed in section 6).
- If you have severe lactic acidosis (too much acid in the blood) before you use this solution for the first time.
- If you have a surgically uncorrectable problem affecting your abdominal wall or cavity or uncorrectable problem that increases risk of abdominal infections.

- If you have documented loss of peritoneal function due to severe peritoneal scarring.

Warnings and precautions

Talk to your doctor before using DIANEAL PD4.

Take special care:

- if you have serious problems affecting your abdominal wall or cavity. For example if you have a hernia or inflammatory condition affecting your intestines.
- if you have an aortic graft placement.
- if you have breathing difficulties.
- if you experience abdominal pain, increased body temperature or notice cloudiness or particles in the drained fluid. This may be a sign of peritonitis (inflamed peritoneum) or infection. You should contact your medical team urgently. Note the batch number of the peritoneal dialysis solution bags you were using and bring them along with the drained fluid bag to your medical team. They will decide if the treatment should be stopped or any corrective treatment started. For example if you have an infection your doctor may perform some tests to find out which antibiotic will be best for you. Until your doctor knows which infection you have, they may give you an antibiotic that is effective against a wide number of different bacteria. This is called a broad-spectrum antibiotic.
- if you have a high risk of severe lactic acidosis (too much acid in the blood). You are at increased risk of lactic acidosis if:
 - you have profoundly low blood pressure or blood-infection that can be associated with acute kidney failure
 - you have an inherited metabolic disease
 - you are taking metformin (a medicine used to treat diabetes)
 - you are taking medicines to treat HIV, especially medicines called NRTIs.
- if you have diabetes and use this solution, the dose of your drugs which regulate the blood sugar level (e.g. insulin) should be evaluated on a regular basis. Especially when the peritoneal dialysis treatment is started, or changed, the dose of your diabetes drugs may need to be adjusted.
- if you have allergy to corn. Stop the infusion immediately and drain the solution from the peritoneal cavity.
- you – possibly together with your doctor – should keep a record of your fluid balance and of your body weight. Your doctor will monitor your blood parameters at regular intervals. Particularly:
 - Salts (e.g. bicarbonate, potassium, magnesium, calcium and phosphate)
 - Parathyroid hormone – responsible for maintaining calcium levels in your body
 - Fats in your blood (lipids).
- if you have high or low levels of calcium in your blood. This solution may influence your calcium levels further.
- not to use more solution than your doctor has prescribed. Symptoms of overinfusion include abdominal distension, a feeling of fullness and shortness of breath.
- your doctor will check your potassium level regularly. If it falls too low they may give you some potassium chloride to compensate.
- because a disorder called Encapsulating Peritoneal Sclerosis (EPS) is a known, rare complication of peritoneal dialysis therapy. You – possibly together with your doctor – should be aware of this possible complication. EPS causes:
 - Inflammation in your abdomen (belly)
 - Thickening of intestines that may be associated with abdominal pain, abdominal distension or vomiting. EPS can be fatal.

Other medicines and DIANEAL PD4

- Tell your doctor if you are taking, have recently taken or might take any other medicines.
- If you use other medicines, your doctor may need to increase their dose. This is because peritoneal dialysis treatment increases the elimination of certain medicines.
- Take care if you use heart medicines known as cardiac glycosides (e.g. Digoxin), you may:
 - need potassium and calcium supplements
 - develop an irregular heartbeat (an arrhythmia)
 - your doctor will monitor you closely during treatment, especially your potassium, calcium and magnesium levels.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. They will advise if this treatment is suitable or not for you.

Driving and using machines

This treatment may cause weakness, blurred vision or dizziness. Do not drive or operate machines if you are affected.

3. How to use DIANEAL PD4

DIANEAL PD4 is to be administered into your peritoneal cavity. This is the cavity in your abdomen (belly) between your skin and the peritoneum. The peritoneum is the membrane surrounding your internal organs such as your intestines and liver.

It is not for intravenous use.

Always use this medicine exactly as instructed by the medical team specialised in peritoneal dialysis. Check with your doctor if you are not sure. Improper clamping or priming sequence may result in infusion of air into the peritoneum, which may result in abdominal pain and/or peritonitis.

If the bag is damaged, you must discard it.

How much and how often

Your doctor will prescribe the appropriate glucose strength and number of bags you must use every day.

If you stop using DIANEAL PD4

Do not stop peritoneal dialysis without the agreement of your doctor. If you stop the treatment it may have life-threatening consequences.

Method of administration

Before use,

- Warm the bag to 37°C. Use the warming plate specially designed for this purpose. Never immerse in water. Never use a microwave oven to warm the bag.
- Remove the overpouch and administer immediately.
- Check that the solution is clear. Do not use the bag if it's not clear.
- Use each bag only once. Discard any unused remaining solution.

Use aseptic technique throughout the administration of the solution as you have been trained. After use, check that the drained fluid is not cloudy.

Compatibility with other drugs

Your doctor may prescribe you other injectable drugs to be added directly into the DIANEAL PD4 bag. In that situation, add the drug through the medication site located at the bottom of the bag. Use the product immediately after addition of the drug. Check with your doctor if you are not sure.

If you use more bags of DIANEAL PD4 than you should in 24 hours

If you infuse too much DIANEAL PD4 you may get:

- abdominal distension
- a feeling of fullness and/or
- a shortness of breath.

Contact your doctor immediately. They will advise you what to do.

If you have any further questions on the use of this product, ask your doctor.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If any of the following happen, tell your doctor or your peritoneal dialysis centre immediately:

- Blood pressure that is higher than usual (Hypertension)
- Swollen ankles or legs, puffy eyes, shortness of breath or chest pain (hypervolaemia)
- Serious illness with blistering of the skin, mouth, eyes and genitals (Stevens–Johnson syndrome)
- Abdominal pain
- Fever
- Inflamed peritoneum (peritonitis).

These are all serious side effects. You may need urgent medical attention.

Side effects that have been reported (occurs in an unknown number of patients treated with DIANEAL PD4):

- Modification of your blood tests:
 - decrease of potassium (hypokalaemia) which can cause muscle weakness, twitching or abnormal heart rhythm
 - decrease in sodium (hyponatraemia) which can cause fatigue, coma, confusion or nausea
 - decrease of chloride (hypochloraemia) which can cause fatigue, coma, confusion or nausea
- Infusion site pain
- Nausea, vomiting, diarrhoea, constipation, dehydration (thirst, dry mouth)
- Decreased blood volume (hypovolaemia)
- Low blood pressure (hypotension)
- Muscle spasms, aching in muscles or bones
- Fluid retention (oedema)
- Distension or discomfort of your abdomen
- Fainting

- Skin disorders such as hives (urticaria), rashes or itching
- Shortness of breath.

Other side effects related to the peritoneal procedure (occurs in an unknown number of patients treated with DIANEAL PD4):

- Infection around the exit site of your catheter, catheter blockage.

If you get any side effects, talk to your doctor or your peritoneal dialysis centre. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Republic of Ireland:

Via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2;

Tel: +353 1 6764971;

Fax: +353 1 6762517;

Website: www.hpra.ie;

E-mail: medsafety@hpra.ie.

Malta

ADR Reporting

www.medicinesauthority.gov.mt/adrportal

United Kingdom

Yellow Card Scheme

www.mhra.gov.uk/yellowcard

5. HOW TO STORE DIANEAL PD4

- Keep this medicine out of the sight and reach of children.
- Store in the original package.
- Do not store above 25°C. Do not refrigerate or freeze.
- Once removed from the overpouch use immediately. Discard any unused solution.
- Do not use this medicine after the expiry date which is stated on the carton label and on the bag after the abbreviation *Exp.* and the symbol . The expiry date refers to the last day of that month.

Dispose of DIANEAL PD4 as you have been trained.

6. Contents of the pack and other information

This leaflet does not contain all the information about this medicine. If you have any questions or are not sure about anything, ask your doctor.

What DIANEAL PD4 contains

DIANEAL PD4 is available in 3 different strengths of glucose.

The formulae are:

DIANEAL PD4	1.36%	2.27%	3.86%
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Formula g/l			
Glucose monohydrate equivalent to Glucose anhydrous	13.6	22.7	38.6
Sodium chloride	5.4	5.4	5.4
Calcium chloride dihydrate	0.184	0.184	0.184
Magnesium chloride hexahydrate	0.051	0.051	0.051
Sodium lactate	4.5	4.5	4.5
mmol/l			
Sodium	132	132	132
Calcium	1.25	1.25	1.25
Magnesium	0.25	0.25	0.25
Lactate	40	40	40
Chloride	95	95	95

The other ingredient is Water for Injections.

What DIANEAL PD4 looks like and contents of the pack

DIANEAL PD4 is packed in a plastic bag available in different volumes.

The solution in the bags is clear and colourless.

Each bag is over-wrapped in an overpouch and supplied in carton boxes.

Volume	Product configuration
1.5 L	Single and twin bags
2.0 L	Single and twin bags
2.5 L	Single and twin bags
3.0 L	Single and twin bags
5.0 L	Single bag

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

Marketing Authorisation Holder

United Kingdom

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

Republic of Ireland and Malta

Baxter Holding B.V.
Kobaltweg 49, 3542CE Utrecht, Netherlands

Manufacturer

United Kingdom, Republic of Ireland and Malta:

Baxter Healthcare S.A., Moneen Road, Castlebar, County Mayo, Ireland

United Kingdom only:

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

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For information about DIANEAL PD4 or to request this leaflet in formats such as audio or large print please contact the Marketing Authorisation Holder: Tel: +44 (0)1635 206345.

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