

**Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986**

This medicine is dispensed with a doctor's prescription only

## DIANEAL PD4 glucose 1.36% solution for peritoneal dialysis

## DIANEAL PD4 glucose 2.27% solution for peritoneal dialysis

## DIANEAL PD4 glucose 3.86% solution for peritoneal dialysis

### Composition:

Each 1 liter contains:			
DIANEAL PD4	3.86%	2.27%	1.36%
gram/liter			
Glucose (as monohydrate)	38.6	22.7	13.6
Sodium chloride	5.38	5.38	5.38
Sodium lactate	4.48	4.48	4.48
Calcium chloride	0.184	0.184	0.184
Magnesium chloride	0.051	0.051	0.051

### Electrolyte content in 1 liter:

mmol/L			
DIANEAL PD4	1.36%	2.27%	3.86%
Sodium	132	132	132
Chloride	95	95	95
Lactate	40	40	40
Calcium	1.25	1.25	1.25
Magnesium	0.25	0.25	0.25

See section 6 for a list of inactive ingredients.

**Read the entire leaflet carefully before you start using this medicine.** This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar to yours.

### 1. What is this medicine intended for?

DIANEAL PD4 solutions are used in cases where peritoneal dialysis is necessary, including cases of patients with kidney failure, severe accumulation of fluids in the body, severely impaired electrolyte balance in the body, and drug intoxication.

**Therapeutic group:**  
hypertonic solutions.

### 2. Before using this medicine

You need medical supervision when using this medicine for the first time.

**Do not use this medicine if:**

- You are sensitive (allergic) to the active ingredients or to any of the other ingredients in this medicine (see section 6).
- You have severe lactic acidosis before you use this medicine for the first time.
- You have a surgically uncorrectable problem affecting your abdominal cavity/wall or an uncorrectable problem that increases your risk of abdominal infection.
- You have ever had loss of peritoneal function due to severe peritoneal scarring.

### Special warnings about using this medicine

**Tell your doctor before you start treatment with DIANEAL PD4, if:**

- you have a serious problem affecting your abdominal wall or cavity. For example, if you have a hernia or an inflammatory condition affecting your intestines.
- you have an aortic graft placement.
- you have breathing difficulties.
- you experience abdominal pain, high fever, or notice cloudiness or particles in the drained peritoneal fluid. These could be signs of peritonitis (inflamed peritoneum) or infection. Contact your medical team immediately. Note the batch number of the peritoneal dialysis solution bag you were using and bring the drained fluid bag with you to your medical team. They will decide if the treatment should be stopped or another treatment started. For example, if you have an infection your doctor may consider performing certain tests to find out which antibiotic will be best for you. Until it is known which infection you have, your doctor will consider prescribing a broad-spectrum antibiotic.
- you have a high risk of developing severe lactic acidosis (too much acid in the blood). You are at increased risk of lactic acidosis if:
  - you have very low blood pressure or a 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.
- you have diabetes and use this solution; the dose of medicines you take to treat your diabetes (such as insulin) should be monitored regularly, especially when the peritoneal dialysis treatment is started, or when the dose is changed. The dose of your diabetes medicines may need to be adjusted accordingly.
- If you are sensitive to corn, stop the dialysis immediately and drain the solution from the peritoneal cavity.
- Keep a record of your fluid balance and of your body weight. Your doctor will monitor your blood test parameters at regular intervals. Particularly:
  - salts (such as bicarbonate, potassium, magnesium, calcium, and phosphate).
  - parathyroid hormone (responsible for maintaining calcium levels in your body).
  - fats in your blood (lipids).
- The calcium levels in your blood are higher or lower than you they should be. Using this medicine may influence your calcium levels further.
- Do not to use more solution than your doctor has prescribed. Symptoms of over-use include abdominal distension, a feeling of fullness, and shortness of breath.
- During the course of this treatment, your doctor will monitor your potassium levels. If they fall too low your doctor may prescribe you some potassium supplements.
- Encapsulating peritoneal sclerosis (EPS) is a known rare complication of peritoneal dialysis treatment. You and your doctor should be aware of the possible complications of EPS.
  - EPS causes:
    - inflammation in your abdomen.
    - thickening of intestines which may be associated with abdominal pain, abdominal distension, or vomiting. EPS can be fatal.

### Other medicines and DIANEAL PD4

**If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist.**

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.

- If you are taking heart medicines known as cardiac glycosides (such as 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 breastfeeding:

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, tell your doctor and ask for advice before taking this medicine. Your doctor will decide if this treatment is right for you.

### Driving and using machines:

DIANEAL PD4 treatment may cause weakness, blurred vision, or dizziness. Do not drive or operate machines if you are affected.

### 3. How to use this medicine?

Always use this medicine exactly as instructed by your doctor and the medical team specialized in peritoneal dialysis. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

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

intestines and liver.

DIANEAL PD4 solution is not for injecting into a vein.

Improper clamping (closing the tubes) or priming sequence (flushing the tubes and removing air) may result in infusion of air into the peritoneal cavity, which may result in abdominal pain and/or peritonitis.

If the bag of solution is damaged, you must discard it.

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

**Do not exceed the recommended dose.**

### Directions for use

**Before using this medicine:**

- Warm the bag to 37°C. Only use dry heat (follow the instructions you are given). Never immerse the bag in water to heat it. Never use a microwave or oven to warm the bag.
- Remove the overpouch and prepare the bag for use.
- Only use if the solution is clear and the package is not damaged.
- Use each bag only once. Discard any unused solution.

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

### Compatibility with other medicines:

Your doctor may prescribe you other medicines to be injected directly into the DIANEAL PD4 bag. In that situation, add the medicine through the appropriate opening located at the bottom of the bag. Use the bag immediately after the medicine has been added. Check with your doctor if you are not sure.

### If you have accidentally taken a higher dose

If you use too much DIANEAL PD4 you may get:

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

If you have taken an overdose of DIANEAL PD4, immediately contact your doctor who will advise you what to do.

Adhere to the treatment as recommended by your doctor.

### If you stop taking this medicine

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

**Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you need them.**

**If you have any further questions about using this medicine, consult your doctor or pharmacist.**

### 4. Side effects

Like with all medicines, using Dianeal PD4 may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

**If you experience any of the following side effects, tell your doctor or your peritoneal dialysis center as soon as possible:**

- blood pressure that is higher than usual
- swollen ankles or legs, puffy eyes, shortness of breath, or chest pain
- 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.

### Additional side effects:

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

- Changes in your blood tests:
  - decrease in potassium levels (hypokalemia) which can cause muscle weakness, twitching, or abnormal heart rhythm
  - decrease in sodium levels (hyponatremia) which can cause fatigue, coma, confusion, or nausea
  - decrease in chloride levels (hypochloremia) which can cause fatigue, coma, confusion, or nausea
- pain around the exit site of your catheter
- nausea, vomiting, diarrhea, constipation, dehydration (dry mouth or thirst)
- decreased blood volume (hypovolemia)
- low blood pressure (hypotension)
- muscle cramps or aching muscles and bones
- edema
- distension or pain in your abdomen
- fainting
- skin disorders such as hives (urticaria), rash, or itching
- shortness of breath

**Undesirable effects related to the peritoneal procedure (occur in an unknown number of patients treated with DIANEAL PD4):**

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

**If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.**

### Reporting side effects

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page ([www.health.gov.il](http://www.health.gov.il)) which links to an online form for reporting side effects. You can also use this link: <https://sideeffects.health.gov.il>

### 5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use this medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
- **Store the bags below 25°C. Do not refrigerate or freeze.**
- Only use if the solution is clear and the package is not damaged.
- Store in the original package.
- Once removed from the overpouch, use immediately. Discard any unused solution.
- Ask your pharmacist how to dispose of medicines you no longer use.

### 6. Additional information

**In addition to the active ingredients, this medicine also contains:**

Water for injection.

### What the medicine looks like and contents of the pack:

- The solution is clear and colorless.
- DIANEAL PD4 solution is packed in a plastic bag and covered with overpouch. It is supplied in a cardboard package.
- Each bag contains 1.5, 2, 2.5, 3, or 5 liters. Not all pack sizes may be marketed.

**Registration holder's name and address:** Teva Medical (Marketing) Ltd., 8 Haorgim Street, Ashdod.

**Manufacturer's name and address:** Baxter Healthcare S.A., Castlebar, Ireland.

**Registration number of the medicine in the Ministry of Health's National Drug Registry:**

DIANEAL PD4 glucose 1.36% solution for peritoneal dialysis: 067.57.28213

DIANEAL PD4 glucose 2.27% solution for peritoneal dialysis: 067.58.28214

DIANEAL PD4 glucose 3.86% solution for peritoneal dialysis: 067.59.28215

This leaflet was reviewed and approved by the Ministry of Health in March 2016 and revised in July 2019 in accordance with Ministry of Health guidelines.