Baxter

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

This medicine is dispensed with a doctor's prescription only

# Nutrineal PD4 with 1.1% amino acids

## Solution for peritoneal dialysis

02727

Composition:
Each liter of solution contains:

| |
|---|
| Tyrosine 300 mg |
| Tryptophan 270 mg |
| Phenylalanine 570 mg |
| Threonine 646 mg |
| Serine 510 mg |
| Proline 595 mg |
| Glycine 510 mg |
| Alanine 951 mg |
| Valine 1393 mg |
| Methionine 850 mg |
| Isoleucine 850 mg |
| Leucine 1020 mg |
| Lysine (hydrochloride) 955 mg |
| Histidine 714 mg |
| Arginine 1071 mg |
| Sodium chloride 5380 mg |
| Calcium chloride dihydrate 184 mg |
| Magnesium chloride hexahydrate 51 mg |
| Sodium (S)-lactate 4480 mg |

Solution composition in mmol/l:

| | |
|---|---|
| Amino acid | 87.16 |
| Sodium | 132 |
| Calcium | 1.25 |
| Magnesium | 0.25 |
| Lactate | 40 |
| Chloride | 105 |

For information about excipients, see section 6.

**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 like yours.

## 1. WHAT IS THIS MEDICINE INTENDED FOR?

- Nutrineal PD4 is a solution for peritoneal dialysis, which does not contain glucose.
- Nutrineal PD4 solution is intended for nutrition in situations of malnutrition in patients suffering from chronic kidney failure (albumin concentration lower than 35 gr/liter), who are treated with peritoneal dialysis.

**Therapeutic group:** Electrolyte solutions

## 2. BEFORE USING THIS MEDICINE

Your doctor will evaluate whether the use of Nutrineal PD4 is the appropriate treatment for you depending on your medical history.

**Do not use this medicine if:**
- You are sensitive (allergic) to any amino acid or any of the other ingredients in this medicine (see section 6).
- Your blood urea level is above 38 mmol/l.
- You suffer from a disorder affecting amino acid metabolism.
- Your blood potassium level is too low.
- You experience symptoms due to urea accumulation in the blood such as loss of appetite, nausea, vomiting.
- Your blood bicarbonate levels are too low.
- You suffer from liver insufficiency.
- You suffer from severe lactic acidosis (high acid level in the blood).
- You have an uncorrected surgical problem affecting your abdominal wall or cavity or an uncorrected problem increasing the risk of abdominal infections.

### Special warnings about using this medicine:

**Tell your doctor:**
- If you experience loss of appetite, nausea or vomiting. Your doctor may need to reduce the use of Nutrineal PD4 or stop Nutrineal PD4 treatment.
- If you experience abdominal pain or notice cloudiness, or particles in the drained fluid. This may be a sign of peritoneal inflammation (peritonitis) or infection. You should contact your medical team urgently. Note the batch number and bring the drained fluid bag to your medical team. The medical team will decide if the treatment should be stopped or if any other treatment is required. For example, if you have an infection your doctor may perform some tests to find out which antibiotic will be best for you. Until the type of infection is determined, your doctor will consider prescribing a broad-spectrum antibiotic to you.
- If you experience a hypersensitivity reaction (an allergic reaction). Your doctor may need to stop Nutrineal PD4 treatment (see also section 4).
- During peritoneal dialysis, your body may lose protein, amino acids, vitamins. Your doctor should advise you whether there is a need to take supplements.
- If you suffer from problems affecting your abdominal wall or cavity, such as a hernia, or a chronic infectious or inflammatory condition affecting your intestines.
- If you have had aortic graft placement.
- If you have severe lung disease (such as emphysema).
- If you have breathing difficulties.
- If you use insulin or any other treatments for hyperglycemia (excess sugar in the blood). Your doctor may need to adjust their dose.
- If you are undergoing treatment for hyperparathyroidism. Your doctor will decide if you can use a dialysis solution with a low calcium content.
- Since one of the rare complications of peritoneal dialysis is encapsulating peritoneal sclerosis (EPS), you, together with your doctor, must be aware of the possible complications of EPS.

- EPS causes:
  - Inflammation in the abdominal area.
  - Thickening of the connective tissue that covers and binds the internal organs and affects their normal movement. Rarely, this condition is life-threatening.
- Your doctor will monitor your potassium levels regularly. If potassium levels decrease to levels which are too low, your doctor will determine the appropriate treatment.
- Your doctor will monitor your blood parameters at regular intervals. He will ensure that they are adequate during your treatment.
- You, together with your doctor, should keep a record of your dietary protein intake, your fluid balance and your body weight.

## Use in children and adolescents:

If you are below the age of 18 years, your doctor will assess the need for Nutrineal PD4 administration.

## Drug interactions:

- **If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.** If you are using other medicines, your doctor may need to increase their dose, since peritoneal dialysis treatment increases the elimination of certain medicines.
- If you are taking medicines for treatment of heart problems of the glycosides group (such as digoxin). Your heart medicine may not be sufficiently effective or its toxicity may be increased. You may:
  - need potassium and calcium supplements.
  - develop an irregular heart rate.

Your doctor will monitor you closely during the treatment, especially your potassium, calcium and magnesium levels.

## Pregnancy and breastfeeding:

Nutrineal PD4 is not recommended during pregnancy or while breastfeeding, unless your doctor advises differently.

## Driving and use of machines:

This treatment may cause weakness, malaise, reduction in blood fluid volume (hypovolemia). Do not drive or operate machines if you experience these effects.

# 3. HOW TO USE THIS MEDICINE?

Always use this medicine according to the instructions of your doctor and the medical team specialized in peritoneal dialysis. Check with your doctor if you are not sure about your dose or about how to use this medicine.

Nutrineal PD4 is to be administered into the peritoneal cavity. This is the abdominal cavity between the skin and the peritoneum. Peritoneum is the tissue surrounding the internal organs, such as intestines and liver.

Nutrineal PD4 solution is not intended for intravenous use.

In case of damage to the solution bag, you should discard it.

**The dosage and manner of treatment will be determined by the doctor only.**
**The usual dosage is generally:**

One bag every day.

Your doctor will re-evaluate your treatment after 3 months if there is no improvement in your nutritional status.

**Do not exceed the recommended dose.**

## Instructions for use

Before use:

- Warm the bag to the temperature of 37ºC. Use only dry heat (according to the instructions you will receive). Never immerse the bag in water to warm it. Do not use microwave to warm the bag.
- Remove the wrapping cover and administer immediately.
- Use only if the solution is clear and packaging is undamaged.
- Use each bag only once.
- Discard any unused remaining solution.

Use aseptic technique throughout the administration of the solution as you have been trained.

## Compatibility with other drugs:

If your doctor prescribed to you other medicines to be injected directly into the Nutrineal PD4 bag: add the medicine through the designated place in the bag.
Use the bag immediately after addition of the medicine.
Check with your doctor if you are not sure.

**If you have accidentally infused a higher dose** (more than one Nutrineal PD4 bag during 24 hours).

If you used too much Nutrineal PD4, you may experience:

- abdominal distension.
- a feeling of fullness.

If you have infused an overdose, contact your doctor immediately. He will advise you what to do.

**If you stop treatment with the medicine**

Do not stop peritoneal dialysis without consulting your doctor. Treatment discontinuation may lead to life-threatening consequences.

Adhere to the treatment as recommended by your doctor.

**Do not take medicines in the dark! Check the label and dose <u>every time</u> you take a 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 Nutrineal 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.

**Inform your doctor or your peritoneal dialysis center as soon as possible if you suffer from any of the following side effects:**

- Abdominal pain
- Bleeding

**Very common side effects** (occur in more than one in 10 patients):

- nausea, vomiting
- anorexia (prolonged eating disorder due to loss of appetite)
- gastritis
- feeling of weakness
- increase in blood fluid volume in the body (hypervolemia)
- high acidity level (acidosis)

**Common side effects** (occur in more than one in 100 patients):

- anemia
- depression
- shortness of breath
- abdominal pain
- decrease in blood fluid volume in the body (hypovolemia)
- decrease in blood potassium level (hypokalemia)
- infection

**Additional side effects** (occur in unknown number of patients):

- peritonitis
- cloudiness of the fluid drained from the peritoneum
- sensation of discomfort in the abdominal area
- fever
- malaise
- itching
- hypersensitivity reaction (an allergic reaction)
- serious allergic reaction causing swelling of the face and throat

**Additional side effects related to peritoneal dialysis procedure:**

- infection at the exit site of the catheter
- catheter-related complications
- decrease in blood calcium level

**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) 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?

- Avoid poisoning! To avoid 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 the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
- **Storage conditions**
  Store below 30ºC.
  Store in the original package.
- Ask the pharmacist how to destroy medicines which are no longer used.

## 6. ADDITIONAL INFORMATION

**In addition to the active ingredients, this medicine also contains:**
Concentrated hydrochloric acid (for pH adjustment), water for injection.

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

- The solution is clear and colorless, packed in a plastic bag.
- The pack is wrapped in a cover (pouch) and supplied in a carton box.
- Each pack contains 2 or 2.5 liters. Not all pack sizes may be marketed.

**Registration holder's name and address:** Baxter HealthCare Distribution Ltd., 34 Jerusalem St., Ra'anana 4350110.

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

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**Registration number of the medicine in the National Drug Registry of the Ministry of Health:** 124.67.28348