**Package Leaflet: Information for the user**

**PHYSIONEAL 40 Glucose 1.36% w/v / 13.6 mg/ml, Solution for Peritoneal Dialysis**
**PHYSIONEAL 40 Glucose 2.27% w/v / 22.7 mg/ml, Solution for Peritoneal Dialysis**
**PHYSIONEAL 40 Glucose 3.86% w/v / 38.6 mg/ml, Solution 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 PHYSIONEAL 40 is and what it is used for
2. What you need to know before you use PHYSIONEAL 40
3. How to use PHYSIONEAL 40
4. Possible side effects
5. How to store PHYSIONEAL 40
6. Contents of the pack and other information


## 1. What PHYSIONEAL 40 is and what it is used for

PHYSIONEAL 40 is a solution for peritoneal dialysis. It removes water and waste products from the blood. It also corrects abnormal levels of different blood components. PHYSIONEAL 40 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.

PHYSIONEAL 40 may be prescribed to you if you have:
- either temporary or permanent kidney failure;
- severe water retention;
- severe disturbances in the acidity or alkalinity (pH) and the level of salts in your blood;
- certain types of drug intoxication where no other treatments are available.

PHYSIONEAL 40 solution has an acidity (pH) close to that of your blood. Therefore it may be particularly useful if you experience inflow pain or discomfort with other more acidic Peritoneal Dialysis solutions.

## 2. What you need to know before you use PHYSIONEAL 40

Your doctor must supervise you the first time you use this product.

**Do NOT use PHYSIONEAL 40**
- If you are allergic to the active substances or any of the other ingredients of this medicine (listed in section 6).
- 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 PHYSIONEAL 40.
Take special care:

- If you have serious problems affecting your abdominal wall or cavity. For example if you have a hernia or a chronic infectious or inflammatory condition affecting your intestines.
- If you have an aortic graft placement.
- If you have severe breathing difficulties.
- If you experience abdominal pain, in**c**reased 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 broadspectrum antibiotic.
- If you have a high level of lactate in your blood. You are at increased risk of lactic acidosis if:
    - you have profoundly low blood pressure
    - you have a blood-infection
    - you have 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 an allergy to maize starch which may result in hypersensitivity reactions, including a serious allergic reaction called anaphylaxis. Stop the infusion immediately and drain the solution from the peritoneal cavity.
- If you have a high level of parathyroid hormone in your blood due to your kidney disease. The low level of calcium in PHYSIONEAL 40 could worsen hyperparathyroidism. Your doctor will monitor levels of parathyroid hormone in your blood.
- 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 and lipids.
- If you have a high level of bicarbonate in your blood.
- 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 levels regularly. If it falls too low they may give you some potassium chloride to compensate.
- Improper clamping or priming sequence may result in infusion of air into the peritoneal cavity, which may result in abdominal pain and/or peritonitis.
- If you infuse unmixed solution, then you should immediately drain the solution and use a newly mixed bag.
- 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.

**Children**

Your doctor will assess the risk against the benefit of using this product if you are under 18 years old.

**Other medicines and PHYSIONEAL 40**

- 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 (eg. 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 level.

**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. Your doctor 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 PHYSIONEAL 40

PHYSIONEAL 40 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.

If the bag is damaged, you must discard it.

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

**Use in children and adolescents**
If you are below 18 years old, your doctor will assess carefully the prescription of this medicine.

**If you stop using PHYSIONEAL 40**
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.
- Use aseptic technique throughout the administration of the solution as you have been trained.
- Prior to beginning an exchange, ensure you clean your hands and the area where your exchange will be performed.
- Prior to opening the overpouch, check for the correct solution type, expiration date, and amount (volume). Lift the dialysate bag to check for any leaks (excess fluid in the overpouch). Do not use the bag if leaks are discovered.
- After removing the overpouch, inspect the container for signs of leakage by pressing firmly on the bag. Check that the interchamber frangible pin is not broken. If the frangible pin is already broken, discard the bag. Do not use the bag if any leak is detected.
- Check that the solution is clear. Do not use the bag if the solution is cloudy or contains particles. Ensure all connections are secure before beginning the exchange.

- Mix the two chambers thoroughly by breaking the interchamber frangible pin. Wait until the upper chamber has completely drained into the lower chamber. Mix gently by pushing with both hands on the lower chamber walls.
- Ask your doctor if you have questions or concerns about this product or how to use it.
- Use each bag only once. Discard any unused remaining solution.
- The solution must be infused within 24 hours after mixing.

  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 PHYSIONEAL 40 bag. In that situation, add the drug through the medication site located on the small chamber, before breaking the interchamber frangible pin. Use the product immediately after addition of the drug. Check with your doctor if you are not sure.

**If you use more bags of PHYSIONEAL 40 than you should in 24 hours**
If you infuse too much PHYSIONEAL 40 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:
- Hypertension (blood pressure that is higher than usual),
- Swollen ankles or legs, puffy eyes, shortness of breath or chest pain (hypervolaemia),
- Abdominal pain,
- Chills (shivering/flu-like symptoms), fever,
- Inflamed peritoneum (peritonitis).

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

If you get any side effects talk to your doctor or your peritoneal dialysis centre. This includes any side effects not listed in this leaflet.

*Common (may affect up to 1 in 10 people)*
- Modification of your blood tests:
  - increase of calcium (hypercalcaemia)
  - decrease of potassium (hypokalaemia) which can cause muscle weakness, twitching or abnormal heart rhythm
  - increase of bicarbonate (alkalosis).
- Weakness, fatigue
- Fluid retention (oedema)
- Weight increase

*Uncommon (may affect up to 1 in 100 people)*
- Decrease in fluid removal on dialysis
- Fainting, dizziness or headache
- Cloudy solution drained from the peritoneum, stomach-ache
- Peritoneal bleeding, pus, swelling or pain around the exit site of your catheter, catheter blockage.
- Nausea, loss of appetite, indigestion, flatulence (passing wind), thirst, dry mouth

- Distension or inflammation of your abdomen, shoulder pain, hernia of the abdominal cavity (groin lump).
- Modification of your blood tests:
  - lactic acidosis
  - increased level of carbon dioxide
  - increase in sugar (hyperglycaemia)
  - increase in white blood cells (eosinophilia)
- Difficulty in sleeping
- Low blood pressure (hypotension)
- Cough
- Aching in muscles or bones
- Swelling of the face or throat
- Rash.

*Other side effects related to the peritoneal procedure*

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

Reporting of side effects
If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed below.

**Republic of Ireland**
HPRA Pharmacovigilance
Website: www.hpra.ie

**United Kingdom**
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

By reporting side effect you can help provide more information on the safety of this medicine.

## 5. How to store PHYSIONEAL 40

- Keep this medicine out of the sight and reach of children.
- Store in the original package.
- Do not store below 4°C.
- 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 PHYSIONEAL 40 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 PHYSIONEAL 40 contains**

The active substances in the mixed peritoneal dialysis solution are:

| | **1.36%** | **2.27%** | **3.86%** |
|---|---|---|---|

| | | | |
|---|---|---|---|
| Glucose monohydrate (g/l) | 15.0 | 25.0 | 42.5 |
| equivalent to Glucose anhydrous (g/l) | 13.6 | 22.7 | 38.6 |
| Sodium chloride (g/l) | 5.38 | | |
| Calcium chloride dihydrate (g/l) | 0.184 | | |
| Magnesium chloride hexahydrate (g/l) | 0.051 | | |
| Sodium bicarbonate (g/l) | 2.10 | | |
| Sodium (S)-lactate solution (g/l) | 1.68 | | |

The other ingredients are Water for Injections and carbon dioxide.

The composition in mmol/l in the **mixed** solution is:

| | **1.36%** | **2.27%** | **3.86%** |
|---|---|---|---|
| Glucose anhydrous (mmol/l) | 75.5 | 126 | 214 |
| Sodium (mmol/l) | 132 | | |
| Calcium (mmol/l) | 1.25 | | |
| Magnesium (mmol/l) | 0.25 | | |
| Chlorides (mmol/l) | 95 | | |
| Bicarbonate (mmol/l) | 25 | | |
| Lactate (mmol/l) | 15 | | |

**What PHYSIONEAL 40 looks like and contents of the pack**

- PHYSIONEAL 40 is a clear, colourless, sterile solution for peritoneal dialysis.
- PHYSIONEAL 40 is packed in a PVC bag with two chambers. The two chambers are separated by a permanent seal.
  You must only infuse PHYSIONEAL 40 once the solutions of the two chambers are fully mixed.
- Each bag is over-wrapped in an overpouch and supplied in a carton box.

| Volume | Number of units per box | Product configuration | Type of connector(s) |
|---|---|---|---|
| 1.5 L | 5 / 6 | Single bag (APD) | luer |
| 1.5 L | 5 / 6 | Twin bag (CAPD) | luer |
| 2.0 L | 4 / 5 | Single bag (APD) | luer |
| 2.0 L | 4 / 5 | Twin bag (CAPD) | luer |
| 2.5 L | 4 / 5 | Single bag (APD) | luer |
| 2.5 L | 4 / 5 | Twin bag (CAPD) | luer |

Not all configurations may be marketed.

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

**Marketing Authorisation Holder**
**United Kingdom**
Vantive Limited,
Wavertree Technology Park,
2 Wavertree Boulevard,
Liverpool, L7 9PE,
United Kingdom

**Republic of Ireland**
Vantive Belgium SRL,
Boulevard d'Angleterre 2,

1420 Braine-l'Alleud,
Belgium

**Manufacturers**

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Moneen Road
Castlebar
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Bieffe Medital SpA,
Via Nuova Provinciale
23034 Grosotto,
Italy

**This leaflet was last revised in 09/2025**

**UK and Ireland:** the use of comma in numbers should be read as dots on the bag and carton labels.

**For information about PHYSIONEAL 40 or to request this leaflet in formats such as audio or large print please contact the Marketing Authorisation Holder: Medical.Information.UKI@vantive.com.**

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