PACKAGE LEAFLET: INFORMATION FOR THE USER

PHYSIONEAL 35 Glucose 1.36% w/v / 13.6 mg/ml CLEAR-FLEX, Solution for Peritoneal Dialysis
PHYSIONEAL 35 Glucose 2.27% w/v / 22.7 mg/ml CLEAR-FLEX, Solution for Peritoneal Dialysis
PHYSIONEAL 35 Glucose 3.86% w/v / 38.6 mg/ml CLEAR-FLEX, 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 35 IS AND WHAT IT IS USED FOR

PHYSIONEAL 35 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 35 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 35 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 35 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 35

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

Do NOT use PHYSIONEAL 35

- 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.

Sometimes treatment with PHYSIONEAL 35 in the CLEAR-FLEX container is not recommended:

- Children requiring fill volumes less than 1600 ml.

Warnings and precautions

Before use, you must:

- Firstly mix the content of the two chambers by opening the long seal;
- Secondly open the short SafetyMoon seal.
- If you infuse unmixed solution (the long-seal between the two chambers is not opened), you may experience abdominal pain. Drain the solution immediately, use a newly mixed bag and inform your doctor straight away.
- If you do not drain the unmixed solution, your blood levels of salts and other chemicals will increase. This will cause undesirable effects such as confusion, drowsiness and irregular heart beat.

Talk to your doctor before using PHYSIONEAL 35.

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, 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 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 corn (maize) 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.
- 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. hydrogen carbonate, potassium, magnesium, calcium and phosphate), parathyroid hormone and lipids.
- If you have a high level of hydrogen carbonate in your blood.
- Not to use more solution than your doctor has prescribed. Symptoms of overinfusion include abdominal distension, 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.
- Improper clamping or priming sequence may result in infusion of air into the peritoneal cavity, which may result in abdominal pain and/or peritonitis.
- 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 35

- 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. Physioneal is not recommended during pregnancy or while breast-feeding unless your doctor advises differently.

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 35

PHYSIONEAL 35 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 35

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 long and short seals are not opened at any point. If one of the seals is opened, even partially, 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 opening the long seal first and then the short SafetyMoon seal.
- 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 35 bag. In that situation, add the drug through the medication site located on the large chamber before opening the long-seal. Disinfect the medication site immediately before injection. 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 35 than you should in 24 hours

If you infuse too much PHYSIONEAL 35 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 happens, 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
- 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.

Malta

ADR Reporting

Website: www.medicinesauthority.gov.mt/adrportal

Republic of Ireland

HPRA Pharmacovigilance, Earlsfort Terrace, IRE – Dublin 2.

Tel: +353 1 6764971, Fax: +353 1 6762517, Website: www.hpra.ie;

E-mail: medsafety@hpra.ie

UK

Yellow Card Scheme

www.mhra.gov.uk/yellowcard

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

5. HOW TO STORE PHYSIONEAL 35

- Keep this medicine out of the sight and reach of children.
- 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 35 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 35 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)	5.67		
Calcium chloride dihydrate (g/l)	0.257		
Magnesium chloride hexahydrate (g/l)	0.051		
Sodium hydrogen carbonate (g/l)	2.10		
Sodium (S)-lactate solution equivalent to sodium (S)-lactate (g/l)	1.12		

The other ingredients are Water for Injections, sodium hydroxide, hydrochloric acid.

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)	1.75		
Magnesium (mmol/l)	0.25		
Chlorides (mmol/l)	101		
Hydrogen bicarbonate (mmol/l)	25		
Lactate (mmol/l)	10		

What PHYSIONEAL 35 Clear-Flex looks like and contents of the pack

- PHYSIONEAL 35 is a clear, colourless, sterile solution for peritoneal dialysis.
- PHYSIONEAL 35 is packed in a non-PVC bag with two chambers. The two chambers are separated by non-permanent seals.
  You must only infuse PHYSIONEAL 35 once the solutions of the two chambers are fully mixed. Only then should you open the short SafetyMoon seal.
- 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	3/4	Single bag (APD)	luer
2.5 L	3/4	Twin bag (CAPD)	luer
3.0 L	3	Single bag (APD)	luer
3.0 L	3	Twin bag (CAPD)	luer
4.5 L	2	Single bag (APD)	luer
5.0 L	2	Single bag (APD)	luer/luer and Homechoice APD set 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

Manufacturer

Vantive Manufacturing Limited
Moneen Road
Castlebar
County Mayo – Ireland

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, United Kingdom: PHYSIONEAL 35 CLEAR-FLEX

Italy: FIXIONEAL 35

This leaflet was last revised in 06/2024

For information about PHYSIONEAL 35 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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