

Consumer Medicine Information

Read this entire leaflet carefully before you start using this medicine.

- Keep this leaflet in safe place. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours
- **If you have any concerns about taking the medicine, ask your Doctor or Renal Nurse.**

WHAT IS IN THIS LEAFLET?

What is PHYSIONEAL 40 and what is it used for?

- Before you use PHYSIONEAL 40
- How to take PHYSIONEAL 40
- Possible side effects
- Storing PHYSIONEAL 40

WHAT IS PHYSIONEAL 40 AND WHAT IT IS USED FOR?

PHYSIONEAL 40 is a solution for peritoneal dialysis. PHYSIONEAL 40 is prescribed to patients whose kidneys are either temporarily or permanently not working. It removes water and waste products from the blood and corrects abnormal blood levels of salt. The higher the glucose strength in the solution, the greater the amount of water that can be removed from the blood.

BEFORE YOU USE PHYSIONEAL 40:

Do not use PHYSIONEAL 40:

There are no times when PHYSIONEAL 40 is not suitable for use during peritoneal dialysis. However, there are several conditions in which special precautions should be taken (see Precautions section below).

Take special care with PHYSIONEAL 40

Your doctor will advise you about particular precautions as they apply to you.

PHYSIONEAL 40 *is for intraperitoneal administration only.*

Product is for single use in one patient only.

- It is generally not advisable to use peritoneal dialysis in the presence of serious conditions affecting the abdominal wall (e.g. skin infections or burns, recent surgery, hernia) or abdominal cavity (e.g. blockage of the intestine, fibrous bands causing abnormal joining of internal surfaces (adhesions), bowel perforation, problems with the diaphragm, tumours and advanced pregnancy) and in severe breathing difficulties, malnutrition or severe disorders affecting fat digestion. In the individual case, the benefits of the patient must be weighed against the possible complications.
- The use of PHYSIONEAL 40 in Clear Flex container is not recommended in

patients requiring a fill volume of < 1600 mL due to the risk of undetected misinfusion (administration of the buffer chamber only).

- Your Doctor will carry out periodic blood tests.
- Keep a written note of your weight, fluid balance and any other measurements, which your doctor has asked you to record. Contact your doctor if your drained volume is more than expected.
- An accurate fluid balance record must be kept and your body weight should carefully be monitored to avoid over and under hydration with severe consequences including congestive heart failure, dehydration and shock.
- If you are a patient with high serum bicarbonate values, your doctor will consider the benefits and risks of use of PHYSIONEAL 40 as it may increase your bicarbonate values.
- Protein, amino acids, water soluble vitamins and other medicines may be removed during peritoneal dialysis and may require replacement.
- If you are a patient with diabetes, blood glucose levels should be monitored and your dosage of insulin or other treatment for hyperglycaemia should be adjusted by your doctor.
- If you are a patient with secondary hyperparathyroidism, the benefits and risks of the use of dialysis solution with 1.25 mmol/L calcium content should be carefully considered as it might worsen hyperparathyroidism.

Pregnancy:

Please consult your doctor. When assessing peritoneal dialysis as a mode of therapy during advanced pregnancy and lactation, the benefits to the patient must be weighed against the possible complications. Women of childbearing potential should be treated with PHYSIONEAL 40 only when adequate contraceptive precautions have been taken.

Breast-feeding:

Please consult your doctor. When assessing peritoneal dialysis as a mode of therapy during lactation, the benefits to the patient must be weighed against the possible complications.

Paediatric:

To date, there are no data from clinical studies in paediatric patients. Safety and effectiveness in paediatric patients has not been established.

Driving and using machines:

Not applicable.

Taking other medicines:

Ask your doctor before taking any other medicine in addition to PHYSIONEAL 40. Some medicines are affected by dialysis. Please inform your doctor if you are taking any other medicine and you will be advised if you need to alter the dose. If you are taking drugs for the heart known as cardiac glycosides (eg. digoxin), your doctor will monitor you closely during treatment.

HOW TO USE PHYSIONEAL 40

General Instructions for use and handling:

- **Product is for single use in one patient only.**
- Prior to exchange assemble supplies on exchange area, wash hands and wipe surface. Prior to opening overpouch, check for the correct solution type, expiration date, and amount (volume).
- The solution should be warmed to 37°C in the overpouch to enhance patient comfort. However, only dry heat (eg heating pad, warming plate) should be used. Solutions should not be heated in water or in a microwave oven.
- Aseptic technique should be employed throughout the peritoneal dialysis procedure.
- Lift the dialysate bag to check for any leaks are contained within the overpouch. If leaks are discovered do not use as sterility may be impaired. In case of damage the container should be discarded.
- Do not administer if the solution is discoloured, cloudy, contains particulate matter or shows evidence of leakage or if seals are not intact.
- The drained fluid should be inspected for the presence of fibrin or cloudiness, which may indicate the presence of peritonitis.
- Discard any unused remaining solution.
- The pH and salts of the solution must be taken into account for compatibility before adding to the solution.
- Contains no antimicrobial preservative.
- The mode of therapy, frequency of treatment, exchange volume, duration of dwell and length of dialysis should be selected by a physician

Viaflex Bag

- Detailed instruction on the Peritoneal Dialysis exchange procedure is given to patients by means of training in a specialised training centre, prior to home use.
- After the removal of the overpouch, inspect the container for signs of leakage. Leaks may occur between the chambers or to the exterior. Check that the interchamber frangible pin is not broken by pressing firmly on the large and small chambers. If the frangible pin is already broken, or if any leak is detected, do not use bag.
- After removal of the overpouch, immediately break the interchamber frangible pin to mix the two solutions. Wait until the upper chamber has completely drained into the lower chamber. Mix gently by pushing with both hands on the lower chamber walls. The intraperitoneal solution must be infused within 24 hours of mixing
- After frangible pin has been broken, check the integrity of the bag for any signs of leakage. If leaks are detected, do not use bag.

- Drugs should be added through the medication port in the glucose chamber before breaking the interchamber frangible pin. The product should be used immediately after any drug addition.
- There is no incompatibility with insulin in PHYSIONEAL in the VIAFLEX container. Consult with pharmacist familiar with peritoneal dialysis, if available. If, in the informed judgement of the physician, it is deemed advisable to introduce additives, use aseptic technique.

Clear Flex Bag

- Detailed instructions on the Peritoneal Dialysis exchange procedure is given to patients by means of training in a specialised training centre, prior to home use.
- After the removal of the overpouch, inspect the container for signs of leakage. Leaks may occur between the chambers or to the external environment. Check that the long and short seals are not opened at any point by pressing firmly on the large and small chambers. If one of the seals is opened, even partially, or if any leak is detected, do not use bag.
- After removal of the overpouch, immediately open the long-seal (interchamber seal) to mix the two solutions and then open the short Safety Moon seal (access seal) to allow administration of the mixed solution. The intraperitoneal solution must be infused within 24 hours of mixing
- Patients must be instructed to open both the long and the short seals prior to infusion. If only the short-seal opens, infusion of the unmixed solution can cause abdominal pain, hypernatremia and severe metabolic alkalosis. In case of infusion of unmixed solution, the patient should immediately drain the solution and use a newly mixed bag.
- After short and long seals have been opened, check the integrity of the bag for any signs of leakage. If leaks are detected, do not use bag. Report and return faulty bags.
- Drugs should be added through the medication site in the larger 'glucose' chamber before opening the interchamber peel seal. The product should be used immediately after any drug addition.
- There is no incompatibility with cefazolin, gentamycin, heparin, low molecular weight heparin, insulin, netilmicin, tobramycin, vancomycin, and PHYSIONEAL in the CLEARFLEX container. Consult with pharmacist familiar with peritoneal dialysis, if available. If, in the informed judgement of the physician, it is deemed advisable to introduce additives, use aseptic technique.

POSSIBLE SIDE EFFECTS:

Like all medicines, PHYSIONEAL 40 can have side effects. Peritoneal dialysis may cause some undesirable effects in addition to its beneficial effects. Contact your doctor if you experience any of the following effects:

- Cloudy effluent, high temperature, feeling sick, stomach pain or shivering/flu-like symptoms
- Redness, pus, swelling or pain around the exit site of your catheter, catheter blockage
- Constipation, intestinal obstruction, shoulder pain, hernia of the abdominal cavity
- Swollen ankles or legs, puffy eyes, shortness of breath or chest pain
- Fall in blood pressure, feeling light headed or dizzy, muscle cramp or thirst
- Bleeding, weakness, fainting, tiredness or headache.

WHAT PHYSIONEAL 40 LOOKS LIKE:

PHYSIONEAL 40 is a sterile, clear, colourless solution for intra-peritoneal administration.

PHYSIONEAL 40 is supplied to you as a two-chamber Viaflex (PVC) bag or two-chamber Clear Flex (non PVC) bag.

Viaflex two-chamber bag consists of a small chamber (containing Solution "A") is fitted with an injection port to enable drugs to be added to the solution of glucose and electrolytes. The large chamber is fitted with a port for connection to a suitable peritoneal dialysis administration set. The bag is sealed inside a transparent overpouch obtained by thermic fusion and made of multilayer copolymers.

Clear Flex two-chamber bag consists of small chamber (containing Buffer solution "B") is fitted with with a port for connection to a suitable peritoneal dialysis administration set. The large chamber (containing Glucose solution "A") is fitted with an injection site to enable drugs to be added to the solution of glucose and electrolytes. The bag is sealed inside a transparent overpouch made of multilayer copolymers.

PHYSIONEAL 40 is available in the following bag sizes and presentations:

Container Type	Viaflex		Clear Flex
	Single bag	Twin bag	Single bag
Therapy type	APD	CAPD	APD only
PHYSIONEAL 40 Glucose 1.36% w/v / 13.6mg/mL, Solution for PD	1.5L, 2L, 2.5L	5L	
PHYSIONEAL 40 Glucose 2.27% w/v / 22.7mg/mL, Solution for PD	1.5L, 2L, 2.5L	5L	
PHYSIONEAL 40 Glucose 3.86% w/v / 38.6mg/mL, Solution for PD	1.5L, 2L, 2.5L	5L	

Ingredients:

Composition of the solution in each compartment before mixing in g/L						
	Viaflex Bag			Clear Flex Bag		
	Glucose 1.36%	Glucose 2.27%	Glucose 3.86%	Glucose 1.36%	Glucose 2.27%	Glucose 3.86%
Small Bag "A"						
Anhydrous Glucose	37.50	62.60	106.50	18.2	30.3	51.5
Calcium Chloride (Dihydrate)	0.507	0.507	0.507	0.245	0.245	0.245
Magnesium Chloride (Hexahydrate)	0.140	0.140	0.140	0.068	0.068	0.068
Large Bag "B"						
Sodium Chloride	8.43	8.43	8.43	19.95	19.95	19.95
Sodium Bicarbonate	3.29	3.29	3.29	9.29	9.29	9.29
Sodium Lactate	2.63	2.63	2.63	6.73	6.73	6.73
Final Solution After Mixing g/L						
Anhydrous Glucose	13.6			22.7		
Sodium Chloride	5.38			5.38		
Calcium Chloride (Dihydrate)	0.154			0.154		
Magnesium Chloride (Hexahydrate)	0.051			0.051		
Sodium Bicarbonate	2.10			2.10		
Sodium Lactate	1.68			1.68		

1000 mL of final solution after mixing corresponds to:

- Viaflex Bag: 362.5 mL of solution A (Glucose) and 637.5 mL of solution B (Buffer).
- Clear Flex Bag: 750 mL of solution A (Glucose) and 250 mL of Solution B (Buffer).
- The pH of the final solution is 7.4.
- Hydrochloric acid and sodium hydroxide are used for pH adjustment in the Clear Flex presentation.

Composition of the final solution after mixing in mmol/L			
	Glucose 1.36%	Glucose 2.27%	Glucose 3.86%
Anhydrous glucose (C ₆ H ₁₂ O ₆)	75.5	126	214
Sodium (Na ⁺)	132	132	132
Calcium (Ca ²⁺)	1.25	1.25	1.25
Magnesium (Mg ²⁺)	0.25	0.25	0.25
Chloride (Cl ⁻)	95	95	95
Bicarbonate (HCO ₃ ⁻)	25	25	25
Lactate (C ₃ H ₅ O ₃ ⁻)	15	15	15
Osmolality*	344 mOsmol/L	395 mOsmol/L	483 mOsmol/L

STORING PHYSIONEAL 40

- Store below 25 °C. Do not freeze.
- Keep PHYSIONEAL 40 out of reach and sight of children.
- Do not use PHYSIONEAL 40 after the expiry date on the label.
- Do not use PHYSIONEAL 40 unless the solution is clear and the container undamaged. Once PHYSIONEAL 40 is removed from its overpouch and mixed it should be used within 24 hours.

If you have further questions please consult your Doctor or Renal Nurse.

Name and Address of Sponsor

Baxter Healthcare Pty Ltd.
1 Baxter Drive
Old Toongabbie, NSW 2146
Australia

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