

**Baxter**



# Physioneal Clear-Flex 5 I for APD\*

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Patient procedure guide

\*Automated Peritoneal Dialysis

Making possible personal.

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**NAME OF THE PATIENT:**

.....

**TELEPHONE NUMBER:**

.....

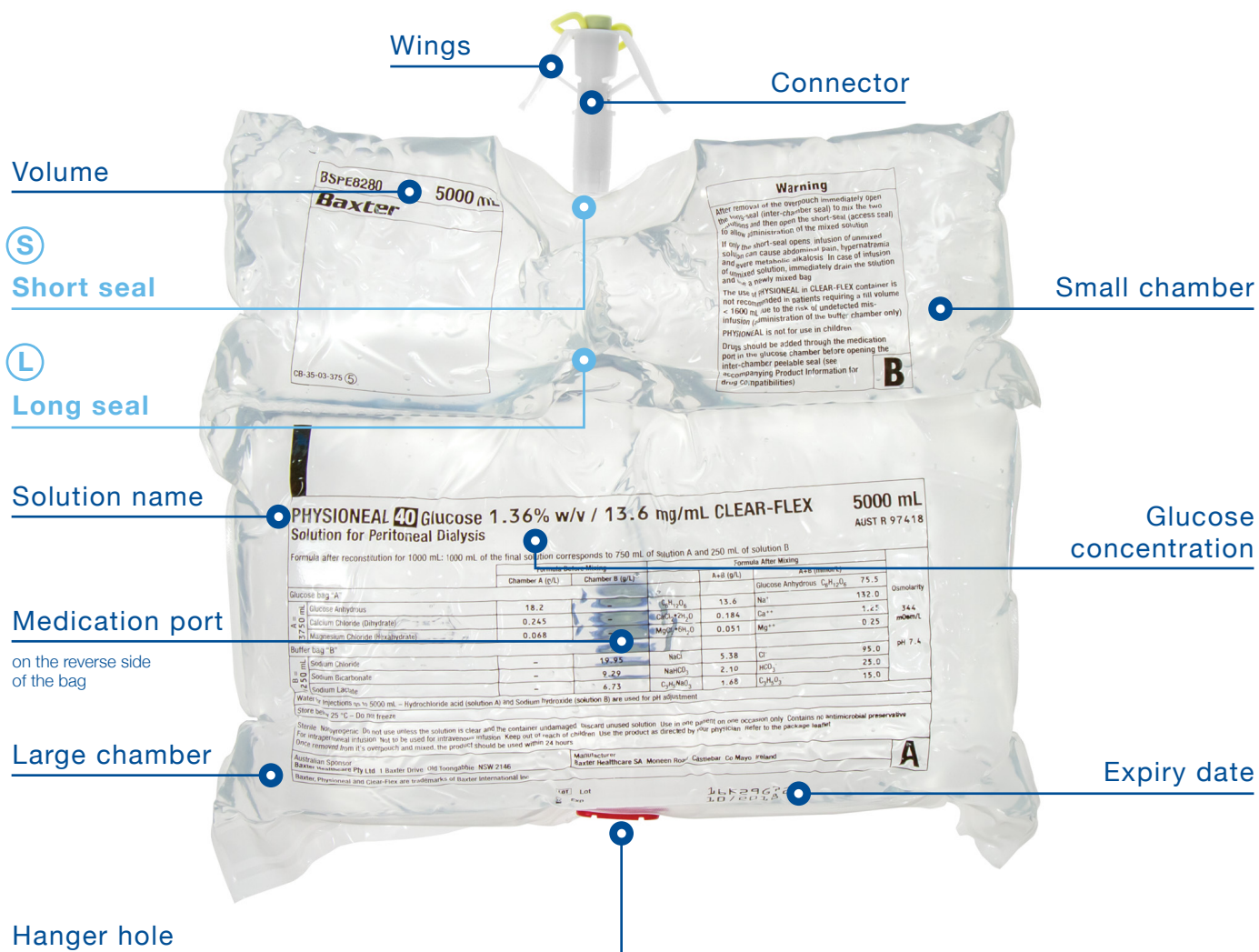
**PERSONAL NOTES:**

.....

**NEXT VISIT:**

.....

# Physioneal Clear-Flex 5l bag



Wings

Connector

Volume

(S)

Short seal

(L)

Long seal

Solution name

Medication port

on the reverse side of the bag

Large chamber

Hanger hole

Small chamber

Glucose concentration

Expiry date

**PHYSIONEAL 40** Glucose 1.36% w/v / 13.6 mg/mL CLEAR-FLEX Solution for Peritoneal Dialysis 5000 mL AUST R 974.18

Formula after reconstitution for 1000 mL: 1000 mL of the final solution corresponds to 750 mL of solution A and 250 mL of solution B

	Formula After Mixing		A+B (g/L)		A+B (g/L)	A+B (mmol/L)
	Chamber A (g/L)	Chamber B (g/L)	Glucose Anhydrous	C <sub>6</sub> H <sub>12</sub> O <sub>6</sub>		
Glucose (big "A")	18.2	—	13.6	13.6	75.5	Osmolality
Glucose Anhydrous	—	—	—	—	132.0	344
Calcium Chloride (Dihydrate)	0.245	—	0.184	0.184	0.25	mmol/L
Magnesium Chloride (Hexahydrate)	0.068	—	0.051	0.051	—	—
Buffer (big "B")	—	19.95	5.38	5.38	95.0	pH 7.4
Sodium Chloride	—	9.25	2.10	2.10	25.0	—
Sodium Bicarbonate	—	6.73	1.68	1.68	15.0	—
Sodium Lactate	—	—	—	—	—	—

Water to inject with up to 5000 mL — Hydrochloric acid (solution A) and Sodium hydroxide (solution B) are used for pH adjustment

Store between 25 °C — Do not freeze

Single Use: Non-sterile. Do not use unless the solution is clear and the container undamaged. Discard unused solution. Use in one patient on one occasion only. Contains no antimicrobial preservative. For intraperitoneal infusion. Not to be used for intravenous infusion. Keep out of reach of children. Use the product as directed by your physician. Refer to the package insert. Once reconstituted from its overpouch and mixed, the product should be used within 24 hours.

Australian Sponsor: Baxter Healthcare Pty Ltd, 1 Baxter Drive, Old Toongabbie, NSW 2146  
 Manufacturer: Baxter Healthcare SA, Monroeville, Australia; Co. Mayo, Ireland

# 1 Gather all your supplies



- PD solution bags
- Homechoice Pro and Homechoice Claria set
- MiniCap (if required)
- Drain option (bag or line)
- Hand sanitiser and antibacterial wipes
- Face mask (optional)

*Supplies may vary*



## Glucose identification system

The glucose strength of the solution is indicated by:

- the coloured band on the carton label
- the number of notches on the carton label
- the coloured pull-ring cap on the bag itself
- the notches on the pull-ring:

1 notch = 1.36% glucose

2 notches = 2.27% glucose

3 notches = 3.86% glucose

- Wash your hands and clean your work surface.
- Place the bags with the connector facing away from you.
- Check each bag for the following:
  1. Expiry date
  2. Solution name\*
  3. Glucose concentration\*
  4. Volume\*

*\*as per prescription*

## 2 Opening the over-pouches and check the Physioneal Clear-Flex bags



- Open the over-pouch of all your bags



- Press firmly on large chamber to check:
  - Long seal is intact
  - Short seal is intact
- Check each bag to make sure:
  - Solution is clear
  - There are no leaks



- Check the connector on each bag for:
  - correct position of the wings
  - presence of the pull-ringas shown on the picture above.
- Make sure you have completed these steps for all your bags.
- If medication is required, it should be added now through the medication port in the larger chamber in line with the prescription and advice of your doctor.

*(See procedure for adding medication on p11).*

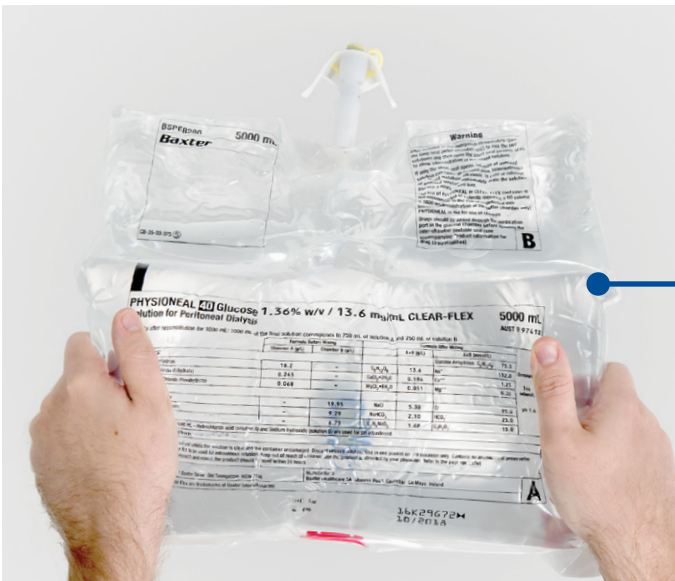


### **DO NOT USE BAG IF:**

- Long and/or short seal is open.
- Presence of **any** sign of leak.
- Connector has a problem.
- The solution is discolored, cloudy, or contains particulate matter.
- Please **report** and **return** any faulty bags to your PD nurse or doctor.

# 3 Mixing the solution

## A. OPEN THE LONG SEAL (L)



- To start opening the long seal, grab each side of the large chamber firmly, turn your hands outwards and push the solution towards the middle of the long seal.

- Now with both hands press on the large chamber to complete the opening of the long seal and to mix the solution.



### DO NOT USE BAG IF:

- Presence of **any** sign of leak.
- Connector has a problem.
- Please **report** and **return** any faulty bags to your PD nurse or doctor.

## B. OPEN THE SHORT SEAL



- Open the short seal by lifting the large chamber, grabbing the material firmly in both hands and rolling the material towards the connector.
- Apply pressure, by leaning over the bag, and pushing the solution towards the short seal to open it.

**Make sure you have completed these steps for all of your bags for this therapy session.**



## C. CHECK FOR LEAKS

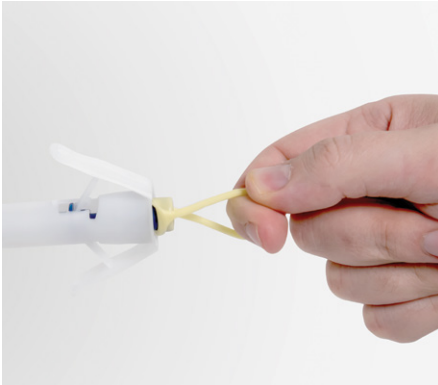


- Check around the bag for any signs of a leak.

**Make sure you have completed these steps for all of your bags for this therapy session.**

## 4

# Connecting the Physioneal Clear-Flex bags



- Wash and disinfect your hands.
- Remove the pull-ring.



- Remove the protector cap from the Homechoice cassette bagline
- Connect the line to the bag until resistance is felt
- Screw the line firmly.



- Close the wings of the bag connector with one hand (you will hear some clicks).

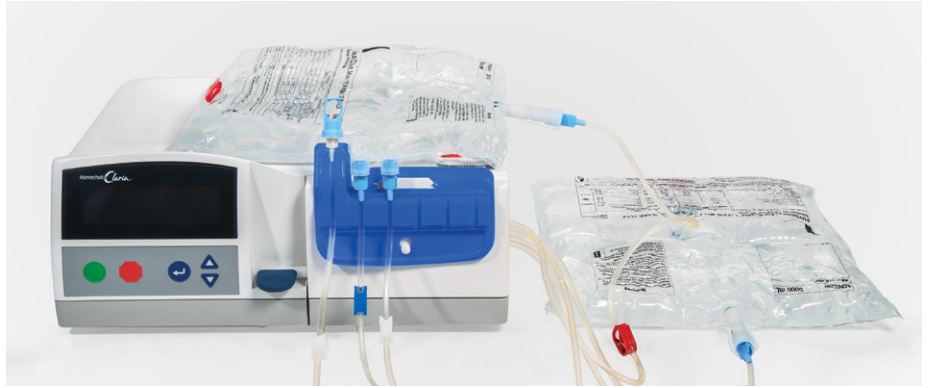
**Check the connection is secure.**

### **IMPORTANT INFORMATION:**

- If leaks are present, you are unable to close the wings of the connector, or there is no flow from solution bag even if wings of connector are closed – discard the HomeChoice/PRO cassette and all solution bags.
- Set up therapy with new HomeChoice/PRO cassette and new solution bags, as directed in HomeChoice/PRO materials.
- Only use the Physioneal connector to connect solution bag to HomeChoice/PRO cassette. Use of other tools to connect may lead to infection.



- Make sure the wings are firmly closed.



- Make sure you have completed these steps for all your Physioneal Clear-Flex bags, and attach them to the appropriate lines.

**The intraperitoneal solution must be infused within 24 hours after mixing.**

**Continue to prepare your therapy as set-out in your Homechoice Pro / Homechoice Claria Guide.**

## A What to do if you infuse unmixed solution

1. **Immediately perform a manual drain.**  
See Homechoice Pro/Homechoice Claria reference material for instructions.
2. **End your therapy early.** See Homechoice Pro/Homechoice Claria reference material for instructions.
3. **You must now infuse a newly mixed solution.\***
4. **Contact your hospital to inform your PD doctor/nurse that you infused unmixed solution.**

*\* Your PD doctor/nurse may instruct you to start your therapy again or to perform a manual exchange. Always follow the instructions that you received from your PD doctor/nurse.*

**Attention:** Infusing unmixed solution can cause abdominal pain. If you experience abdominal pain during or just after infusion, then check that both of the seals on all the bags are open.

**YOUR CONTACT NAME AT THE HOSPITAL:**

.....

**TELEPHONE NUMBER:**

.....

**If you experience abdominal pain or any other side effect,  
please follow the steps 1 to 4 specified above.**

## B Procedure for adding medication to Physioneal Clear-Flex bags

If medication is prescribed it must be added before opening the long seal



- Position the bag with the blue medication port facing upwards.



- Disinfect your hands.
- Remove the blue pull-ring from the medication port.



- Disinfect the medication port.



- Inject medication directly through the medication port.
- Do not inject anything other than the prescribed medication.

**Return to Procedure for use: “3. How to mix the solution”. The product should be used immediately after any drug addition.**

## c Practical tips when using Physioneal Clear-Flex bags

### Storing your boxes



#### Care should be taken when storing your boxes:

- Store boxes flat.
- Do not store below 4°C.
- Do not heat the bag in the microwave.

### Handling Bags



#### Care should be taken when handling Physioneal Clear-Flex bags:

- Carry the bag with two hands.
- Never carry the bag by the over-pouch alone.
- Never carry the bag by the connector.

### Placing On The Homechoice



- Ensure heater-bag is resting on the temperature detector.
- To minimise heating time, please store your bags for your next therapy at room temperature.
- Do not place more than 1 bag on the heater.

## Disposing of empty bags



- Place over-pouches and empty bags flat, one on top of the other. These can be placed in an empty box or discarded according to local procedure.

**Discard any unused remaining solution**

# Physioneal Clear-Flex Handling Information

## DO



Keep boxes flat when carrying



Set down boxes carefully



Stack boxes flat Maximum 9 layers



**Instruction for non-regular shipment**  
Minimum 4 boxes on pallet  
Maximum 9 layers of boxes

## DO NOT



Do not carry boxes from only one end



Do not drop or throw boxes



Do not stack boxes on side



**Instruction for non-regular shipment**  
Do not ship single boxes



# Consumer Medicine Information

## PHYSIONEAL 40 Peritoneal Dialysis Solution

### 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, netilmycin, 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 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%
<b>Small Bag "A"</b>						
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
<b>Large Bag "B"</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	38.6
Sodium Chloride	5.38	5.38	5.38
Calcium Chloride (Dihydrate)	0.184	0.184	0.184
Magnesium Chloride (Hexahydrate)	0.051	0.051	0.051
Sodium Bicarbonate	2.10	2.10	2.10
Sodium Lactate	1.68	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
- STORING PHYSIONEAL 40

	Glucose 1.36%	Glucose 2.27%	Glucose 3.86%
Anhydrous glucose (C <sub>6</sub> H <sub>12</sub> O <sub>6</sub> )	75.5	26	214
Sodium (Na <sup>+</sup> )	132	132	132
Calcium (Ca <sup>++</sup> )	1.25	1.25	1.25
Magnesium (Mg <sup>++</sup> )	0.25	0.25	0.25
Chloride (Cl <sup>-</sup> )	95	95	95
Bicarbonate (HCO <sub>3</sub> <sup>-</sup> )	25	25	25
Lactate (C <sub>3</sub> H <sub>5</sub> O <sub>3</sub> <sup>-</sup> )	15	15	15
Osmolarity*	344 mOsmol/L	395 mOsmol/L	483 mOsmol/L

- 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**

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Australia

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