

CONSUMER MEDICINE INFORMATION

Physioneal 40 Peritoneal Dialysis Solution

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

- Keep this leaflet. 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

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

If you have any concerns about taking the medicine, ask your Doctor or Renal Nurse.

Keep this leaflet in a safe place. You may wish to read it again.

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.

Physioneal 40 is supplied to you as a two-chamber PVC bag. The 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.

Physioneal 40 is provided as single two-chamber bags containing 1500 mL, 2000 mL, 2500 mL or twin two-chamber bags containing 1500 mL, 2000 mL, 2500 mL.

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.*

- 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.
- 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.

Precautions for use:

Detailed instruction and training on the peritoneal dialysis exchange procedure will be given to you, in a specialised training centre, before you use Physioneal 40 at home.

- You should practice aseptic technique throughout the bag change procedure.
- The solution should be warmed in the overpouch to body temperature before use.
- In the case of damage, the container should be discarded before use.
- After removal of the overpouch, verify that the interchamber frangible pin is not broken. If the seal is already broken, discard the bag.
- Just before infusion prepare the solution by breaking the interchamber frangible pin.
The intraperitoneal solution must be infused within 24 hours after mixing.
Do not infuse without breaking the interchamber frangible pin. If the solution is accidentally infused without breaking the interchamber frangible pin, immediately drain the solution and use a newly mixed bag. Inform your physician.
- Drugs should be added through the medication port in the SMALL chamber before breaking the interchamber frangible pin. Drug compatibility will be checked by your doctor. The product should be used immediately after any drug addition.
- Do not administer unless the solution is clear.
- Discard any unused remaining solution.
- Use in one patient on one occasion only.
- The mode of therapy, frequency of treatment, exchange volume, duration of dwell and length of dialysis will be selected by your doctor.

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.

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

The solution should be warmed in the overpouch to body temperature before use.

After removal of the overpouch, verify that the interchamber frangible pin is not broken. If the seal is already broken, discard the bag. Then prepare the solution just before infusion by breaking the interchamber frangible pin. The intraperitoneal solution must be infused within 24 hours after mixing.

The solution is for intraperitoneal administration only, that is to say, the solution is infused in your peritoneal cavity through a catheter. It is important to take your solutions as directed by your doctor. He will have told you which strengths of glucose and which volume of solution you must use, as well as how often each day you must change bags. The normal number of exchanges is 4 or 5 per day, using a fill volume of 2 to 2.5 litres.

To reduce the risk of dehydration, it is important to use the solution(s) your doctor has chosen for you.

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. It is in a two-chamber flexible plastic container with or without a second plastic bag attached for drainage.

It is available in the following bag sizes: 1.5, 2.0, 2.5 litres.

And the following strengths:

Physioneal 40 Glucose 1.36% w/v / 13.6mg/mL, Solution for Peritoneal Dialysis
Physioneal 40 Glucose 2.27% w/v / 22.7mg/mL, Solution for Peritoneal Dialysis
Physioneal 40 Glucose 3.86% w/v / 38.6mg/mL, Solution for Peritoneal Dialysis

Ingredients:

The active substances are:

	Physioneal 40 Glucose		
	1.36%	2.27%	3.86%
Small bag "A"			
Glucose Monohydrate	41.25 g/L	68.85 g/L	117.14 g/L
Equivalent to Anhydrous Glucose	37.5 g/L	62.6 g/L	106.5 g/L
Calcium Chloride Dihydrate	0.507 g/L	0.507 g/L	0.507 g/L
Magnesium Chloride Hexahydrate	0.140 g/L	0.140 g/L	0.140 g/L
Large bag "B"			
Sodium Chloride	8.43 g/L	8.43 g/L	8.43 g/L
Sodium Bicarbonate	3.29 g/L	3.29 g/L	3.29 g/L
Sodium Lactate	2.63 g/L	2.63 g/L	2.63 g/L

Final solution after mixing

	Physioneal 40 Glucose		
	1.36%	2.27%	3.86%
Glucose Monohydrate	15.0 g/L	25.0 g/L	42.5 g/L
Equivalent to anhydrous glucose	13.6 g/L	22.7 g/L	38.6 g/L
Sodium Chloride	5.38 g/L	5.38 g/L	5.38 g/L
Calcium Chloride Dihydrate	0.184 g/L	0.184 g/L	0.184 g/L
Magnesium Chloride Hexahydrate	0.051 g/L	0.051 g/L	0.051 g/L
Sodium Bicarbonate	2.10 g/L	2.10 g/L	2.10 g/L
Sodium Lactate	1.68 g/L	1.68 g/L	1.68 g/L

1000 mL of final solution after mixing corresponds to 362.5 mL of solution A and 637.5 mL of solution B. The pH of the final solution is 7.4.

Composition of the final solution after mixing in mmol/l

Anhydrous Glucose (C ₆ H ₁₂ O ₆)	75.5 mmol/L	126 mmol/L	214 mmol/L
Sodium (Na ⁺)	132 mmol/L	132 mmol/L	132 mmol/L
Calcium (Ca ⁺⁺)	1.25 mmol/L	1.25 mmol/L	1.25 mmol/L
Magnesium (Mg ⁺⁺)	0.25 mmol/L	0.25 mmol/L	0.25 mmol/L
Chloride (Cl ⁻)	95 mmol/L	95 mmol/L	95 mmol/L
Bicarbonate (HCO ₃ ⁻)	25 mmol/L	25 mmol/L	25 mmol/L
Lactate (C ₃ H ₅ O ₃ ⁻)	15 mmol/L	15 mmol/L	15 mmol/L
Osmolarity	344 mOsmol/L	395 mOsmol/L	483 mOsmol/L

Other Ingredients:

Water for Injections

STORING PHYSIONEAL 40

Keep Physioneal 40 out of reach and sight of children. Do not freeze.

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 pharmacist.

Name and Address of Sponsor

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This leaflet was approved on: 12 May 2005

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