

# PHYSIONEAL 40

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

### 1. Why am I using PHYSIONEAL 40?

PHYSIONEAL 40 contains the active ingredients glucose, calcium chloride dihydrate, magnesium chloride hexahydrate, sodium chloride, sodium lactate and sodium bicarbonate. PHYSIONEAL 40 is used in peritoneal dialysis in patients with acute or chronic kidney failure.

For more information, see Section [1. Why am I using PHYSIONEAL 40?](#) in the full CMI.

### 2. What should I know before I use PHYSIONEAL 40?

Do not use PHYSIONEAL 40 if you have ever had an allergic reaction to PHYSIONEAL 40 or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use PHYSIONEAL 40?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with PHYSIONEAL 40 and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use PHYSIONEAL 40?

- Follow all directions given to you by your doctor or nurse or pharmacist carefully.
- PHYSIONEAL 40 Solutions are intended for use via PD catheter only. Aseptic techniques must be maintained during the bag connection in order to reduce the risk of infection.
- Do not use PHYSIONEAL 40 if the solution is discoloured, cloudy, contains particulate matter or shows evidence of leakage or if seals are not intact.
- PHYSIONEAL 40 bags should be used only once and any unused solution remaining must be discarded.

More instructions can be found in Section [4. How do I use PHYSIONEAL 40?](#) in the full CMI.

### 5. What should I know while using PHYSIONEAL 40?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, surgeon, anaesthetist, dentist, pharmacist or nurse you visit that you are using PHYSIONEAL 40.</li><li>• Follow the instructions from your doctor or nurse on how to carry out peritoneal dialysis.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not use PHYSIONEAL 40 for intravenous administration.</li><li>• Do not heat PHYSIONEAL 40 in water or in a microwave.</li><li>• Do not stop using PHYSIONEAL 40 without letting your doctor know.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Clear Flex bags: Store below 25°C. Do not freeze.</li><li>• PVC bags: Store below 30°C. Do not freeze.</li><li>• Do not use after the expiry date on the bag.</li></ul>

For more information, see Section [5. What should I know while using PHYSIONEAL 40?](#) in the full CMI.

### 6. Are there any side effects?

You may experience side effects such as hernia, shoulder pain, peritonitis, abdominal pain, inflammation around the catheter, fluid and electrolyte imbalances as part of peritoneal dialysis treatment.

For more information, including full list of possible side effects and what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# PHYSIONEAL 40

**Active ingredient(s):** *Glucose, calcium chloride dihydrate, magnesium chloride hexahydrate, sodium chloride, sodium lactate and sodium bicarbonate*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using PHYSIONEAL 40. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using PHYSIONEAL 40.**

### Where to find information in this leaflet:

- [1. Why am I using PHYSIONEAL 40?](#)
- [2. What should I know before I use PHYSIONEAL 40?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use PHYSIONEAL 40?](#)
- [5. What should I know while using PHYSIONEAL 40?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using PHYSIONEAL 40?

PHYSIONEAL 40 contains the active ingredients glucose, calcium chloride dihydrate, magnesium chloride hexahydrate, sodium chloride, sodium lactate and sodium bicarbonate. PHYSIONEAL 40 is a solution for peritoneal dialysis.

PHYSIONEAL 40 is used in peritoneal dialysis in patients with acute or chronic kidney failure.

## 2. What should I know before I use PHYSIONEAL 40?

### Warnings

#### Do not use PHYSIONEAL 40 if:

- the expiry date on the pack has passed.
- the solution is discoloured, cloudy, contains particulate matter or shows evidence of leakage between chambers or to the exterior or if seals are not intact.
- you are allergic to glucose, calcium chloride dihydrate, magnesium chloride hexahydrate, sodium chloride, sodium lactate and sodium bicarbonate, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- you have known allergies to corn or corn products as the solution contains dextrose (glucose monohydrate).
- you have a disorder of metabolism known as lactic acidosis.
- you have any issues that prevents effective dialysis or increase the likelihood of the infection.

- you have any changes in peritoneal function.

#### Check with your doctor if you:

- have injury or surgery or congenital anomalies (birth defects) related to abdominal wall or cavity
- a history of abdominal operations with fibrous adhesions (scar tissue)
- hernia
- faecal fistula (a passageway from your stomach or bowel to the skin)
- abdominal wall infection
- colostomy or ileostomy
- frequent episodes of diverticulitis
- inflammatory bowel diseases (Crohn's disease, ulcerative colitis, diverticulitis)
- peritonitis
- intra-abdominal tumours
- large polycystic kidneys
- you have a lung disease (especially pneumonia)
- have severe abdominal pain, abdominal distension or vomiting. This can be a sign of encapsulating peritoneal sclerosis, a complication of the peritoneal dialysis therapy that can be fatal
- aortic graft replacement
- weight loss, particularly when adequate nutrition is impossible
- you have very high levels of fat in the blood (hyperlipidaemia)
- take any medicines for any other condition

Your doctor will monitor your parathyroid hormone, electrolytes levels (particularly bicarbonate, potassium, magnesium, calcium and phosphate) and blood profile, as well as other indicators of your health to ensure they are in safe ranges.

**PHYSIONEAL 40 does not contain potassium. In patients with normal or low potassium levels, your doctor may consider adding potassium to the dialysis solution to prevent the occurrence of very low potassium levels.**

It is important to keep a record of your fluid levels to avoid overhydration or underhydration. This may lead to serious consequences such as heart failure, dehydration and shock. Your doctor will monitor your weight to ensure that you are using the right fluid volumes.

Peritoneal dialysis can lead to a **loss of proteins, amino acids, water-soluble vitamins and other medicines**. An adequate diet or nutritional supplements may be recommended in order to avoid deficiency states. Some changes in your medicine may be needed.

Aseptic techniques must be maintained during the bag connection in order to reduce the risk of infection. If you experience peritonitis, your doctor may prescribe antibiotics.

Open both the long and short seals prior to infusion. If only the short seal opens, infusion of the unmixed solutions can cause abdominal pain, hypernatremia and severe metabolic alkalosis. In case of infusion of unmixed solution, immediately drain the solution and use a newly mixed bag.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor them. See additional information under Section [6. Are there any side effects?](#)

### **Pregnancy and breastfeeding**

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

## **3. What if I am taking other medicines?**

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Peritoneal dialysis can lead to a **loss of proteins, amino acids, water-soluble vitamins and other medicines**. An adequate diet or nutritional supplements may be recommended in order to avoid deficiency states. Some changes in your medicine may be needed.

If you have diabetes requiring insulin, carefully monitor your insulin requirements during and following dialysis with glucose-containing solutions. Your doctor will monitor your blood potassium levels carefully in patients with cardiac glycosides.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect PHYSIONEAL 40.**

## **4. How do I use PHYSIONEAL 40?**

### **How much to use**

Your doctor will determine the method, formulation, duration and frequency of use and the required volume of solution and time in the peritoneal cavity (dwell time).

**You must follow the procedures and instructions given by your doctor or nurse every time you do peritoneal dialysis. Contact your doctor if you are having problems or are unsure about any of the techniques.**

## **When to use PHYSIONEAL 40**

PHYSIONEAL 40 should be used, as prescribed by your doctor.

**You must follow the procedures and instructions given by your doctor or nurse every time you do peritoneal dialysis. Contact your doctor if you are having problems or are unsure about any of the techniques or your prescription.**

## **How to use PHYSIONEAL 40 for PD**

PHYSIONEAL 40 Solutions are intended for intraperitoneal administration only. Do not use for intravenous administration.

Aseptic techniques must be maintained during the bag connection in order to reduce the risk of infection.

To reduce discomfort on administration, the solution may be warmed to a temperature of 37°C prior to use. This should be done using dry heat ideally with a warming cabinet. Do not heat PHYSIONEAL 40 in water or in a microwave. Do not use PHYSIONEAL 40 if the solution is discoloured, cloudy, contains particulate matter or shows evidence of leakage or if seals are not intact.

Prior to exchange assemble supplies on exchange area, wash hands and wipe surface. Prior to use, check for the correct solution type, expiration date, and amount (volume).

Open overpouch and remove contents. Ensure the pull ring is attached to the solution administration port. Do not use if pull ring is not attached as sterility may be impaired.

The drained fluid should be checked for cloudiness, which may indicate the presence of infection (peritonitis). PHYSIONEAL 40 bag should be used once, and any unused portion of the solution must be discarded.

### **PVC Bag – Instruction for use and handling**

- Specialised staff at the training centre will train you in the use of PHYSIONEAL 40 prior to home use.
- Only use PHYSIONEAL 40 if the container is undamaged. 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.

### Clear Flex bag – Instruction for use and handling

- Specialised staff at the training centre will train you in the use of PHYSIONEAL 40 prior to home use.
- Only use PHYSIONEAL 40 if the container is undamaged.
- Check that the long and short seals are not open 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
- 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.

### If you forget to use PHYSIONEAL 40

PHYSIONEAL 40 should be used, as prescribed by your doctor.

If you forget to do an exchange or have used too little solution, contact your doctor for guidance.

### If you use too much PHYSIONEAL 40

Overdose by over infusion of a PHYSIONEAL 40 Solutions into the peritoneal cavity is characterised by abdominal pain and abdominal stretching and shortness of breath.

If you allow too much solution to flow into the peritoneal cavity, the excess can easily be drained into the empty bag. However, overdose can result in too much body fluid, electrolyte imbalance and high blood sugar. In this case, please consult your doctor.

If you think that you have used too much PHYSIONEAL 40, you may need urgent medical attention.

#### You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## 5. What should I know while using PHYSIONEAL 40?

### Things you should do

Follow the procedures and instructions from your nurse or doctor on how to carry out peritoneal dialysis with PHYSIONEAL 40 every time you do it. PHYSIONEAL 40

dialysis solutions should be used, as prescribed by your doctor.

Body weight, blood sugar, potassium, calcium, magnesium, phosphate, bicarbonate, parathyroid hormone, and blood profile, as well as other indicators of your health should be monitored regularly by your doctor.

### Call your doctor straight away if you:

- Do not feel well or develop any unwanted side effects (see section [6. Are there any side effects?](#)). Seek medical attention immediately.

Remind any doctor, surgeon, anaesthetist, dentist, pharmacist, or nurse you visit that you are using PHYSIONEAL 40.

### Things you should not do

- Do not use PHYSIONEAL 40 for intravenous administration.
- Do not heat PHYSIONEAL 40 in water or in a microwave.
- Do not stop using PHYSIONEAL 40 without letting your doctor know.

### Looking after your medicine

- Clear Flex bags: Store below 25 °C. Do not freeze.
- PVC bags: Store below 30 °C. Do not freeze.
- Do not use after the expiry date on the bag.

### Keep it where young children cannot reach it.

Follow the instructions in the carton on how to take care of your medicine properly.

### When to discard your medicine

PHYSIONEAL 40 bags should be used once, and any unused portion of the solution must be discarded.

### Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

Less serious side effects	What to do
General disorders and administration conditions <ul style="list-style-type: none"><li>• facial swelling</li></ul>	

<ul style="list-style-type: none"> <li>chills</li> <li>feeling unwell</li> <li>thirst</li> </ul> <p><b>Gastrointestinal disorders</b></p> <ul style="list-style-type: none"> <li>reflux (heartburn)</li> <li>nausea</li> </ul> <p><b>Skin disorders</b></p> <ul style="list-style-type: none"> <li>pruritus (severe itching)</li> <li>sweating</li> <li>skin lesion</li> <li>rash</li> <li>swelling under skin</li> </ul> <p><b>Musculoskeletal disorders</b></p> <ul style="list-style-type: none"> <li>shoulder pain</li> <li>muscle cramping</li> </ul> <p><b>Neurological disorders</b></p> <ul style="list-style-type: none"> <li>weaknesses</li> <li>headache</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>
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<ul style="list-style-type: none"> <li>blockage of gut</li> </ul> <p><b>Metabolic disorders</b></p> <ul style="list-style-type: none"> <li>alkalosis</li> <li>acidosis</li> <li>weight loss</li> <li>high blood sugar</li> <li>weight gain</li> <li>muscle pain</li> <li>enlarge heart</li> <li>high blood pressure</li> <li>low blood pressure</li> </ul>	
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**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

### Serious side effects

Serious side effects	What to do
<p><b>Peritoneal dialysis procedure related disorders</b></p> <ul style="list-style-type: none"> <li>peritoneal membrane failure</li> <li>bleeding</li> <li>infections</li> <li>infection around the catheter</li> <li>catheter blockage</li> <li>hernia</li> <li>fainting</li> </ul> <p><b>Renal disorders</b></p> <ul style="list-style-type: none"> <li>fluid retention</li> <li>dehydration</li> <li>electrolyte and fluid imbalances</li> </ul> <p><b>Cardiovascular disorder</b></p> <ul style="list-style-type: none"> <li>irregular heartbeat</li> </ul> <p><b>Musculoskeletal disorders</b></p> <ul style="list-style-type: none"> <li>increase muscle tone</li> </ul> <p><b>Infections</b></p> <ul style="list-style-type: none"> <li>peritonitis (with cloudy fluid in the drainage bag, abdominal pain, nausea and vomiting, fever, chills and, if untreated, generalised blood poisoning)</li> </ul> <p><b>Respiratory disorders</b></p> <ul style="list-style-type: none"> <li>shortness of breath</li> <li>cough</li> </ul> <p><b>Gastrointestinal disorders</b></p>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

## 7. Product details

This medicine is only available with a doctor's prescription.

### What PHYSIONEAL 40 contains

<b>Active ingredient (main ingredient)</b>	Glucose, calcium chloride dihydrate, magnesium chloride hexahydrate, sodium chloride, sodium lactate and sodium bicarbonate
<b>Other ingredients (inactive ingredients)</b>	Hydrochloric acid, sodium hydroxide, water for injections

**Do not take this medicine if you are allergic to any of these ingredients.**

### What PHYSIONEAL 40 looks like

PHYSIONEAL 40 is a sterile, clear, colourless solution.

PHYSIONEAL 40 is supplied as a two-chamber PVC bag or two-chamber Clear Flex bag.

The PVC bag container volumes after reconstitution: 1500 mL (544 mL of solution A and 956 mL of solution B), 2000 mL (725 mL of solution A and 1275 mL of solution B) and 2500 mL (906 mL of solution A and 1594 mL of solution B).

The Clear Flex bag Container volume after reconstitution is 5000 mL (3750 mL of solution A and 1250 mL of solution B).

PHYSIONEAL 40 Glucose 1.36% w/v Peritoneal Dialysis  
Solution Bag AUST R 97418

PHYSIONEAL 40 Glucose 2.27% w/v Peritoneal Dialysis  
Solution Bag AUST R 97426

PHYSIONEAL 40 Glucose 3.86% w/v Peritoneal Dialysis  
Solution Bag AUST R 97431

PHYSIONEAL 40 Glucose 1.36% w/v Peritoneal Dialysis  
Solution Twin Bag AUST R 119077

PHYSIONEAL 40 Glucose 2.27% w/v Peritoneal Dialysis  
Solution Twin Bag AUST R 119078

PHYSIONEAL 40 Glucose 3.86% w/v Peritoneal Dialysis  
Solution Twin Bag AUST R 119079

### **Who distributes PHYSIONEAL 40**

VANTIVE Pty Ltd  
1 Baxter Drive  
Old Toongabbie NSW 2146  
AUSTRALIA

This leaflet was prepared in December 2025.