

Package insert

CAPD/DPCA 3
with 4.25 % glucose anhydrous

Solution for peritoneal dialysis

Please read the following instructions carefully, as they contain important information on the use of this medicinal product.

If you have any further questions, please contact your doctor or pharmacist.

Package insert

CAPD/DPCA 3

with 4.25 % glucose anhydrous

Composition of the medicinal product

1 litre contains:

	CAPD / DPCA 3
Sodium chloride	5.786 g
Sodium lactate	3.925 g
Calcium chloride 2 H ₂ O	0.2573 g
Magnesium chloride 6 H ₂ O	0.1017 g
Glucose-monohydrate	46.75 g
^ anhydrous glucose	42.50 g
Na ⁺	134 mmol/l
Ca ⁺⁺	1.75 mmol/l
Mg ⁺⁺	0.5 mmol/l
Cl ⁻	103.5 mmol/l
Lactate	35 mmol/l
theoretical Osmolarity	511 mOsm/l
pH ≈	5.5

- b) Other ingredients:
 Hydrochloric acid
 Sodium hydroxide
 Water for injections

Presentation form and pack sizes

*CAPD/DPCA 2 sleep•safe: In cartons containing
 2 bags of 5000 ml each*

*CAPD / DPCA 2 stay• safe: In cartons containing
 6 bags of 1500 ml each
 4 bags of 2000 ml each
 4 bags of 2500 ml each
 2 bags of 5000 ml each*

Solution for peritoneal dialysis

Marketing authorisation holder:

Fresenius Medical Care (UK) Limited,
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 Huthwaite,
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 Nottinghamshire. NG17 2HU.

Manufacturer:

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Indications

What are CAPD Solutions used for

CAPD 3 is a solution for Continual Ambulatory Peritoneal Dialysis or CAPD. These solutions are used in patients with poor or no kidney function (end-stage chronic renal failure). The solution helps with the removal of waste products and fluid from the blood and corrects abnormal levels of salts in the blood. The higher the strength of glucose the greater the amount of fluid is removed from the blood.

Contraindications

When must CAPD / DPCA 3 not be used?

For this specific solution:

CAPD/DPCA 3 must not be used in severe potassium deficiency in the blood (hypokalaemia), marked excess of calcium (hypercalcaemia), or low blood pressure (hypovolaemia).

For peritoneal dialysis in general:

You should not proceed with peritoneal dialysis using this solution if you have one or more of the following disorders.

- Recent abdominal trauma, i.e. surgery, injury, burns, intestinal obstruction (ileus), tumour or hernia.
- Extensive inflammation of the abdominal skin (dermatitis) in the region of the catheter.
- Inflammation of the lining of the abdominal cavity (peritonitis)
- Inflammatory disease of the intestine (Crohn's disease, ulcerative colitis, diverticulitis).
- Perforation of the abdominal cavity.
- A history of multiple operations with adhesions or fibrous adhesions.
- Internal or external abdominal fistula i.e. connection between internal abdominal organs or between an internal abdominal organ and the exterior in the abdominal region.
- Diseases of the lung (especially pneumonia).
- Generalised blood poisoning (sepsis)
- Acidification of the blood (Lactacidosis)
- Recent extreme malnutrition and weight loss
- Your cholesterol levels are high.
- If the amounts of urea and other nitrogenous waste products in your blood can not be managed by peritoneal dialysis.

Should any of the above-mentioned disorders develop during peritoneal dialysis treatment, please consult your doctor who will decide how to proceed.

Warnings and precautions

In the following circumstances CAPD/DPCA 3 should only be used after consulting your doctor

In the following situations CAPD / DPCA 3 should only be used under certain conditions and with extreme care. Please ask your doctor about them. This also applies if these events have occurred in the past:

Loss of electrolytes due to severe vomiting or diarrhoea, (this may necessitate the temporary use of a potassium-containing peritoneal dialysis solution).

In cases of excess calcium in the blood (hypercalcaemia), for example as a consequence of high doses of calcium-containing phosphate binders and/or Vitamin D , it may be necessary to use a solution with a lower calcium content either temporarily or permanently.

Please note that premature discontinuation of peritoneal dialysis therapy may have life-threatening consequences if no other renal replacement therapy is carried out.

What do you have to take into account during pregnancy and breast-feeding?

In the later stages of pregnancy, peritoneal dialysis should be performed only after consulting with the doctor who is treating you.

What needs to be considered in children and the elderly?

In children, the dialysate volume should be reduced in accordance with age, size and body weight (see also "Dosage and administration").

The increased incidence of hernia in elderly patients should be taken into account before starting peritoneal dialysis.

What precautions have to be taken?

It is advisable to keep exact records of fluid balance and body weight to avoid excessive loss of fluid (dehydration) or increased fluid load (hyperhydration) with potentially life-threatening consequences.

Levels of electrolytes, such as sodium, potassium, magnesium, calcium, phosphate, the acid-base balance, the level of blood sugar , concentrations of creatinin and urea, and serum protein levels should be monitored regularly.

If a drug or other substance has to be added to the dialysis solution (only to be undertaken on the instructions of a doctor), a check for possible incompatibilities must be carried out first. A solution to which other substances have been added must always be prepared fresh and used immediately (not stored).

Plastic containers may occasionally become damaged during transport from the manufacturer to the dialysis centre or during storage in the hospital. This can result in contamination, with growth of micro-organisms in the dialysis solution.

Therefore a careful inspection must always be carried out prior to connection of the container and use of the solution for peritoneal dialysis. Any damage, however minor, to the closure, container welds or corners, must be noted, as it may indicate contamination of the solution has occurred.

Bags with cloudy contents must never be used. Only use the peritoneal dialysis solution if the container and closure exhibit no signs of damage.

Aseptic conditions must be maintained during exchange of the dialysate bag in order to reduce the risk of infection.

The peritoneal dialysis solution CAPD / DPCA 3 is not to be used for intravenous infusion. Any unused portion of the solution is to be discarded.

What special precautions should be taken if you are a diabetic?

In diabetic patients, the daily insulin dose must be adjusted to allow for the increased glucose uptake.

Does CAPD / DPCA 3 affect your ability to drive a car or operate machines?

No. When used as directed, it does not impair driving ability or the operation of machines.

Drug interactions

Do other medicines affect the action of CAPD / DPCA 3?

If calcium compounds or vitamin D are used during CAPD/DPCA 3 treatment, the blood levels of calcium can increase and hypercalcaemia may occur;

Simultaneous administration of drugs that increase the flow of urine (diuretics) can help maintain residual renal function, but may also result in water and electrolyte imbalances.

Levels of potassium must be carefully monitored when heart drugs based on digitalis are being taken at the same time because the sensitivity to these drugs is increased if potassium levels are low.

Dosage and administration

The mode of therapy, frequency of administration, dwell time and exchange volumes required will be specified by the attending physician. Unless otherwise directed by your doctor, the following instructions apply. Please observe them strictly, as otherwise CAPD / DPCA 3 cannot work properly.

How much CAPD / DPCA 3 should you use and how often?

Unless otherwise directed, 2000 ml of solution should be infused per exchange. If distension pain occurs at the start of treatment,

the dialysate volume can be temporarily reduced to 500 - 1500 ml per exchange. In children, a dose of 500 - 1500 ml (30 – 40 ml/kg body weight), depending on age, size and body weight, is recommended.

In large adults and/or patients who tolerate larger volumes, a dose of 2500 – 3000 ml may be given.

If a machine is used for intermittent or continuous cycling peritoneal dialysis, it is advisable to use larger volume bags.

Peritoneal dialysis is a long-term therapy involving repeated administration by the same method. In case of dwell times of 4 - 8 hours, a dose of 2000 ml solution may be used four times in every 24 hour period (a total dose of 8000 ml), or smaller or larger doses as appropriate (dose given merely as a guide, dosage must be adjusted for the individual patient).

How and when should CAPD / DPCA 3 be used?

Warm the ready-to-use solution to body temperature and then infuse the appropriate dose into the peritoneal cavity over 5 - 20 minutes using a peritoneal dialysis catheter . Depending on the doctor's instructions, the dose should dwell in the peritoneal cavity for 4 - 8 hours (equilibrium time) and then be drained and replaced.

Depending on the fluid status and electrolyte concentrations, CAPD/DPCA 3 can be used together with another peritoneal dialysis solution of lower glucose content (i.e. with lower fluid removal capacity) or other potassium and sodium concentrations. To protect the peritoneum and avoid the danger of dehydration, high glucose concentrations as present in CAPD/DPCA 3, should be used as sparingly as possible. Generally one or two exchanges with high glucose concentration are sufficient, other solutions of lower glucose concentration are used for the other exchanges.

To enable you to carry out peritoneal dialysis yourself, you will need to be shown how to handle the equipment and will practice with sample bags. The doctor is responsible for ensuring that you have mastered the necessary techniques sufficiently; you will be taught by specially trained nurses or carers. However, as you perform the peritoneal dialysis yourself, it is important to always discuss any problem or questions that you may have with your attending doctor.

How long should you use CAPD / DPCA 3?

Dialysis using the prescribed doses should be performed daily.

Peritoneal dialysis should be continued for as long as renal replacement therapy is required.

Mistakes in use

What to do if too much CAPD / DPCA 3 has been used?

If too much dialysate flows in, it can be easily drained off into the empty bag. If however, bag exchanges have been carried out too frequently, states of dehydration and/or disorders of blood electrolyte content (electrolyte imbalance) can occur. Immediate medical emergency treatment is then required.

What should you do if you have used too little CAPD / DPCA 3 or have forgotten an exchange?

In this case, it is generally advisable to shorten the dwell time of the following exchange so that the total dialysate volume per 24 hours (e.g. 4 x 2000 ml) can be achieved. Please contact your doctor who will tell you exactly what to do.

What do you have to consider if you interrupt or discontinue treatment?

In this case, life-threatening fluid overload (hyperhydration) with accumulation of fluid in tissues and lungs (oedema) and cardiac decompensation and / or other symptoms of uraemia, can result.

Side effects

CAPD / DPCA 3 is a solution of electrolytes whose composition is essentially similar to that found in human blood.

What side effects may occur during use of CAPD / DPCA 3?

Possible side effects may result from the peritoneal dialysis process itself, or may be induced by the solution.

Peritoneal dialysis treatment related side effects:

Very common complications of all peritoneal dialysis therapy, including treatment with CAPD / DPCA 3 are peritonitis and infections of the catheter exit site and tunnel. Cloudiness of the drained dialysate may be an initial symptom of peritonitis; later, fever, abdominal pain and malaise (generally feeling unwell) may develop or, in very rare cases, generalised blood poisoning (sepsis). Please report even the slightest sign of cloudiness to your doctor immediately, close the bag containing the drained dialysate with a sterile cap and take it along with you.

Please look after your catheter daily as instructed by your doctor (e.g. change the dressing) and check the exit site, because inflammation of the site or the tunnel along the line of the catheter can occur. If you see any sign of inflammation, please inform your doctor as soon as possible.

A relative loss of proteins (5-15 g/day), amino acids (1.2 – 3.4 g/day) and water-soluble vitamins is commonly unavoidable during peritoneal dialysis. To prevent deficiencies, an adequate diet must be ensured. Protein deficiency (hypoproteinaemia) may occur if protein intake does not compensate for the protein loss.

The transport characteristics of the peritoneal membrane may change during long-term peritoneal dialysis primarily indicated by a

loss of ultrafiltration. In severe cases peritoneal dialysis must be stopped and hemodialysis commenced.

Other potential side effects of peritoneal dialysis therapy are abdominal distension and a feeling of fullness (abdominal pain), in- and outflow disturbances of the dialysis solution, hernia, shoulder pain, breathing difficulties caused by elevation of the diaphragm, diarrhoea or constipation. Once again, please consult your doctor about the necessary counter-measures.

Peritoneal dialysis solution related side effects:

The dialysis solution may cause disturbances of electrolyte balance, such as potassium deficiency (hypokalaemia) and of fluid balance. In combination with an increased calcium intake, e.g. through administration of calcium-containing phosphate binders, high calcium blood levels (hypercalcaemia) may develop. These disturbances can be readily overcome by using other peritoneal dialysis solutions containing lower calcium levels in the case of hypercalcaemia, a changed diet or peritoneal dialysis solutions containing potassium in the case of hypokalaemia.

In terms of fluid imbalances, dehydration and fluid overload may develop. Severe dehydration, (especially in treatment with solutions of higher glucose concentration) may take the form of low blood pressure, increased heart rate, dizziness and muscle cramps; the opposite, fluid overload, may cause increased body weight, high blood pressure, swollen legs and shortness of breath.

Occurrence or exacerbation of existing lipid metabolism disorders such as disturbances of fat levels in the blood (dyslipoproteinaemia) or increased concentration of fats in the blood (hyperlipidaemia) is very common.

Because of the continuous uptake of glucose from the dialysis solution obesity might rarely occur if the diet of the patient is not adapted to the increased caloric load.

If you observe side effects that are not listed in this package insert, please inform your doctor or pharmacist.

Shelf-life

The expiry date for this pack is printed on each bag. Do not use CAPD / DPCA 3 after this date!

When should you not use CAPD / DPCA 3 even before the expiry date?

Do not use any bag which is damaged or which contains cloudy solution. Return the bag to your doctor or pharmacist.

How should you store CAPD / DPCA 3?

Do not store above 25 °C. Do not refrigerate or freeze.

Only use CAPD / DPCA 3 if the solution is clear and the container undamaged.

Keep CAPD / DPCA 3 out of the reach of children!

Date of last revision:

11th November 1999

POM