# CAPD/DPCA 2/3/4 STAY SAFE LINK SOLUTION FOR PERITONEAL DIALYSIS

**CAPD/DPCA 2**: Each 1 litre contains Calcium Chloride Dihydrate 0.2573 g, Sodium Chloride 5.786 g, Sodium Lactate Solution 7.85 g, Magnesium Chloride Hexahydrate 0.1017 g, Glucose Monohydrate 16.5 g
**CAPD/DPCA 3**: Each 1 litre contains Calcium Chloride Dihydrate 0.2573 g, Sodium Chloride 5.786 g, Sodium Lactate Solution 7.85 g, Magnesium Chloride Hexahydrate 0.1017 g, Glucose Monohydrate 46.75 g
**CAPD/DPCA 4**: Each 1 litre contains Calcium Chloride Dihydrate 0.2573 g, Sodium Chloride 5.786 g, Sodium Lactate Solution 7.85 g, Magnesium Chloride Hexahydrate 0.1017 g, Glucose Monohydrate 25.0 g

**What is in this leaflet**



## 1. What CAPD/DPCA 2/3/4 is used for

CAPD/DPCA 2/3/4 **is used for cleaning the blood** via the peritoneum in patients with end-stage chronic kidney failure of any origin. This type of blood cleaning is called peritoneal dialysis.

## 2. How CAPD/DPCA 2/3/4 works

Peritoneal dialysis is a way to remove waste products from your blood when your kidneys can no longer do the job adequately eg. kidney failure. During peritoneal dialysis, the blood is filtered in the peritoneum – the membrane that lines the cavity. The peritoneal cavity stores the dialysis fluid and the filtration takes place across the peritoneum. Toxins and excess fluid cross the peritoneal membrane during the prescribed dwell time.

A permanent tube, or catheter, is inserted into the peritoneal cavity. Through which, dialysis fluid is fed into the cavity and left to absorb the impurities from the blood. Later, the fluid is drained-off into a bag and replaced with fresh fluid. This process, of filling and draining, can be done manually during the day.

## 3. Before you use CAPD/DPCA 2/3/4

*When you must not use it*

- if the level of **potassium in your blood is very low**
- if the level of **calcium in your blood is very high**
- if you suffer from **disorders of lactate metabolism**
- if you have **fructose metabolism disorders** (hereditary fructose intolerance)

*Before you start to use it*

**Peritoneal dialysis treatment must not be started if you have**

- alterations in the abdominal region such as:
  - injuries, or after surgery
  - severe burns
  - large, inflammatory skin reactions
  - inflammation of the peritoneum
  - non-healing, weeping wounds
  - umbilical, inguinal or diaphragmatic hernias
  - tumours in the abdomen or bowel
- inflammatory bowel diseases
- intestinal obstruction
- lung diseases, particularly pneumonia
- blood poisoning caused by bacteria
- extremely high levels of fat in the blood
- poisoning due to urine products in the blood which cannot be treated by blood cleaning
- severe malnutrition and loss of weight, particularly if adequate intake of food containing proteins is not possible.

Pregnancy and breast-feeding:

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. There are no data from the use of CAPD/DPCA 2/3/4 in pregnant women or during lactation period. If you are pregnant, you should not use CAPD/DPCA 2/3/4 unless your doctor considers this absolutely necessary.

It is unknown whether CAPD/DPCA 2/3/4 active substances/ metabolites are excreted in human milk. Breast-feeding is not recommended for mothers on peritoneal dialysis.

*Taking other medicines*

Tell your doctor if you are taking, have recently taken or might take any other medicines.

Because peritoneal dialysis may influence the effects of medicines, your doctor may need to change their dosages, especially those of:

- **Medicines for heart failure**, such as digitoxin. Your doctor will check the level of potassium in your blood and, if necessary, will take appropriate measures.
- **Medicines that influence calcium levels** such as those containing calcium or vitamin D.
- **Medicines that increase the excretion of urine** such as diuretics.
- **Medicines** taken by mouth **that lower blood sugar levels** or insulin. Your blood sugar level should be measured regularly.

## 4. How to use CAPD/DPCA 2/3/4

*How much to use*

Always use this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

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

If tension occurs in the abdominal region your doctor may reduce the volume.

**Continuous ambulatory peritoneal dialysis (CAPD):**

• **Adults:** Unless otherwise prescribed, patients will receive an infusion of 2000 ml solution per exchange four times a day. After a dwell time between 2 and 10 hours the solution will be drained.

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• **Children:** In children the solution volume per exchange should be prescribed according to age and body surface area (BSA).
For initial prescription, the volume per exchange should be 600 – 800 ml/m² BSA with 4 exchanges per day.
There are no special dosage recommendations for elderly patients.
Use CAPD/DPCA 2/3/4 in **the peritoneal cavity only.**
Use CAPD/DPCA 2/3/4 only if the solution is clear and the bag is undamaged.

**Handling Instruction**
***stay•safe*® system for continuous ambulatory peritoneal dialysis (CAPD):**
The solution bag is first warmed to body temperature. For bags with a volume up to 3000 ml this should be done by using an appropriate bag warmer. The heating time depends on the bag volume and the used bag warmer (for a 2000 ml bag with a starting temperature of 22°C is approximately 120 min). More detailed information can be obtained from the operating instructions of the bag warmer. Use of microwaves is not recommended due the risk of local overheating. After warming the solution you can start with the exchange of the bags.

1. Check the solution bag (label, the expiry date and ensure that the solution is clear) ➧ open the overwrap and the packaging of the disinfection cap.
2. Clean hands with an antimicrobial washing solution.
3. Place the DISC into the organiser (suspend solution bag from the upper hole of the infusion pole ➧ unroll the line "solution bag-DISC" ➧ place the DISC into the organiser ➧ afterwards place drainage bag into lower holder of the infusion pole).
4. Place catheter extension into one of the two inserts of the organiser. Place the new disinfection cap into the other free insert.
5. Disinfect your hands and remove protection cap of the DISC.
6. Connect catheter extension to the DISC.
7. Open the clamp on extension ➧ position "●" ➧ outflow procedure starts.
8. After completion of the outflow: Flush ➧ position "●●" ➧ flush fresh dialysate to the drainage bag (approx. 5 seconds).
9. Inflow ➧ position " ○◑● " ➧ connection between solution bag with the catheter.
10. Security step ➧ position "●●●●" ➧ automated closing of the catheter extension with the PIN.
11. Disconnection ➧ remove the protection cap from the new disinfection cap and screw it onto the old one. Unscrew catheter extension from the DISC and screw onto the new disinfection cap.
12. Close the DISC with the open end of the protection cap (which has remained in the right hole of the organizer).
13. Check the drained dialysate for clarity and weight and, if the effluent is clear, discard it.

Each bag should be used only once and any unused solution remaining must be discarded.

After appropriate training, CAPD/DPCA 2/3/4 can be used independently at home. Ensure that you follow all the procedures you learnt during training and maintain hygienic conditions when exchanging bags.
Always check the drained dialysate for cloudiness. See section "*Before you use CAPD/DPCA 2/3/4*".

*When to use it*
Use as directed by your doctor.

*How long to use it*
Continue using CAPD/DPCA 2/3/4 for as long as your doctor recommends.

*If you forget to use it*
Try to attain the volume of dialysate prescribed for each 24-hour period in order to avoid the risk of possibly life-threatening consequences. You should check with your doctor if you are not sure.
If you have any further questions on the use of this product, ask your doctor, pharmacist or nurse.

*If you use too much (overdose)*
If you allow too much solution to flow into the peritoneal cavity, the excess can be drained off.
If you use too many bags please contact your doctor as this can result in fluid and/or electrolyte imbalances.

**5. While you're using it**
*Things you must do*
Take your medicine exactly as your doctor has told you.
Tell all the doctors, dentists and pharmacists treating you that you are taking CAPD/DPCA 2/3/4.
Tell your doctor immediately if you become pregnant while taking this medication.
Inform your doctor immediately:

- if you have a **severe loss of electrolytes (salts)** due to vomiting and/or diarrhoea
- if you have an **overactive parathyroid** or a **high calcium level in your blood** a temporary or permanent change to a solution with a lower calcium content may be necessary.
- if you have an **inflammation of the peritoneum,** recognisable by a

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cloudy dialysate, abdominal pain, fever, feeling unwell or in very rare cases blood poisoning.
Please show the bag containing the drained dialysate to your doctor.

- if you 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.

Peritoneal dialysis can lead to a **loss of proteins, amino acids** and **water-soluble vitamins.** An adequate diet or nutritional supplements are recommended to avoid deficiency states.
Your doctor will check your electrolyte (salt) balance, blood cell counts, kidney function, body weight and nutritional state.
CAPD/DPCA 2/3/4 contains 15/42.5/22.73 g glucose in 1000 ml solution. Depending on the dosage instructions and the pack size used up to 30/85/45.46 g glucose (CAPD, 2000 ml *stay•safe link*) are supplied to the body with each bag. This should be taken into account in patients with diabetes mellitus.

*Things you must not do*
Do not stop taking the medicine unless advised by your doctor.
Do not take any new medicines without consulting your doctor.
Do not give CAPD/DPCA 2/3/4 to anyone else, even if they have the same symptoms or condition as you.

*Things to be careful of*
Driving and using machines:
CAPD/DPCA 2/3/4 has no or negligible influence on the ability to drive or use machines.

## 6. Side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following side effects may occur as a result of the treatment in general:
**very common** (may affect more than 1 in 10 people):
• inflammation of the peritoneum with signs of cloudiness of the drained dialysate, abdominal pain, fever, feeling unwell or in very rare cases blood poisoning.
Please show the bag containing the drained dialysate to your doctor.
• inflammation of the skin at the catheter exit site or along the length of the catheter, recognisable by redness, swelling, pain, weeping or crusts.
• hernia of the abdominal wall
Please contact your doctor immediately if you notice any of these side effects.

Other side effects of the treatment are:
**common** (may affect up to 1 in 10 people)**:**
• problems with inflow or outflow of the dialysate
• sensation of stretching or fullness of the abdomen
• shoulder pain
**uncommon** (may affect up to 1 in 100 people):
• diarrhoea
• constipation
**not known** (frequency cannot be estimated from available data):
• breathing difficulties due to elevation of the diaphragm
• encapsulating peritoneal sclerosis, possible symptoms may be abdominal pain, abdominal distension or vomiting

The following side effect may occur when CAPD/DPCA 2/3/4 is used:
**very common** (may affect more than 1 in 10 people)**:**
• potassium deficiency
**common** (may affect up to 1 in 10 people)**:**
• high blood sugar levels
• high blood fat levels
• weight gain
• increase in calcium levels, hypercalcaemia
**uncommon** (may affect up to 1 in 100 people):
• body fluid levels too low, which can be recognised by rapid weight loss
• dizziness
• low blood pressure
• rapid pulse
• body fluid levels too high which can be recognised by rapid weight gain
• water in the tissues and lung
• high blood pressure
• breathing difficulties
**not known** (frequency cannot be estimated from available data)
• overactive parathyroid with potential disturbances of bone metabolism.

**Reporting of side effects**
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.
You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers →Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].
By reporting side effects you help provide more information on the safety of this medicine.

## 7. Storage & Disposal of CAPD/DPCA 2/3/4

Keep this medicine out of the sight and reach of children.
Do not use this medicine after the expiry date which is stated on the bag and

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carton after "EXP". The expiry date refers to the last day of that month.
Store below 30°C. Do not refrigerate or freeze.
The solution must be used immediately after opening.
No special requirements for disposal.

**8. Product Description**
*What it looks like*
The solution is clear and colourless to slightly yellow.
The theoretical osmolarity of CAPD/DPCA 2/3/4 is 358/511/401 mOsm/l, the pH is about 5.5.

**CAPD/DPCA 2/3/4 is available in the following application systems and pack sizes per carton:**

| ***stay•safe link*** |
|---|
| 6 × 2000 ml bags |

*Ingredients*
The active substances in one litre solution are:

| **CAPD/DPCA 2/3/4:** | |
|---|---|
| Calcium chloride dihydrate | 0.2573 g |
| Sodium chloride | 5.786 g |
| Sodium-(S)-lactate-solution (3.925 g Sodium-(S)-lactate) | 7.85 g |
| Magnesium chloride hexahydrate | 0.1017 g |
| **CAPD/DPCA 2:** Glucose monohydrate (15.0 g glucose) Up to 0.75 g fructose | 16.5 g |
| **CAPD/DPCA 3:** Glucose monohydrate (42.5 g glucose) Up to 2.1 g fructose | 46.75 g |
| **CAPD/DPCA 4:** Glucose monohydrate (22.73 g glucose) Up to 1.1 g fructose | 25.0 g |

**These quantities of active substances are equivalent to:**
CAPD/DPCA 2/3/4:
1.75 mmol/l calcium, 134 mmol/l sodium, 0.5 mmol/l magnesium, 103.5 mmol/l chloride and 35 mmol/l (S)-lactate.
CAPD/DPCA 2: 83.2 mmol/l glucose
CAPD/DPCA 3: 235.8 mmol/l glucose
CAPD/DPCA 4: 126.1 mmol/l glucose

The other ingredients of CAPD/DPCA 2/3/4 are water for injections, hydrochloric acid and sodium hydroxide.

**MAL Number**
MAL16105023AZ (CAPD/DPCA 2 Stay Safe Link Solution for Peritoneal Dialysis)
MAL16105024AZ (CAPD/DPCA 3 Stay Safe Link Solution for Peritoneal Dialysis)
MAL16105025AZ (CAPD/DPCA 4 Stay Safe Link Solution for Peritoneal Dialysis)

**9. Manufacturer**
Fresenius Medical Care Production Sdn. Bhd.
Lot 34618, PT 29466 Techpark @ Enstek, 71760 Bandar Enstek, Negeri Sembilan, Malaysia.

**10. Product Registration Holder**
Fresenius Medical Care Malaysia Sdn. Bhd.,
Second Floor, Axis Technology Centre, Lot 13, Jalan 51A/225,
46100 Petaling Jaya, Selangor, Malaysia.

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