

CAPD/DPCA 18 SLEEP SAFE PERITONEAL DIALYSIS SOLUTION**CAPD/DPCA 18 STAY SAFE PERITONEAL DIALYSIS SOLUTION**

Glucose Monohydrate (46.75g), Magnesium Chloride (Hexahydrate) 0.1017g,

Calcium Chloride Dihydrate 0.1838g, Sodium Chloride 5.786g, Sodium Lactate Solution 7.85g

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What CAPD/DPCA 18 is used for

CAPD/DPCA 18 is used for **cleaning the blood** via the peritoneum in patients with end-stage chronic kidney failure. This type of blood cleaning is called peritoneal dialysis.

How CAPD/DPCA 18 works**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. A microwave oven must not be used to warm the solution due to the risk of local overheating. After warming the solution you can start with the exchange of the bags.

1. Check the solution bag (label, expiry date, clearness of the solution, bag and overwrap not damaged) ♦ open the overwrap of the bag and packaging of the disinfection cap/closure cap.
2. Wash your 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 ♦ 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/closure 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 “○○●” ♦ connect the 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/closure cap and screw it onto the old one ♦ unscrew the catheter extension from the DISC and screw it 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 organiser).
13. Check the drained dialysate for clarity and weight and if the effluent is clear discard it.

sleep•safe system for automated peritoneal dialysis (APD):

For the setup of the *sleep•safe* system please refer to its operating instructions.

2-1. Preparation of the solution

Check the solution bag (label, expiry date, clearness of the solution, bag and overwrap not damaged). ♦ Place the bag on a solid surface. ♦ Open the overwrap of the bag. ♦ Wash your hands with an antimicrobial washing lotion. ♦ Check whether the solution is clear and that the bag is not leaking.

3-2. Unroll tubing of bag.**4-3. Remove the protection cap.****5-4. Insert connector in free tray port.****6-5. The bag is now ready for use with the *sleep•safe* set.**

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

After appropriate training, CAPD/DPCA 18 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 18*”

Before you use CAPD/DPCA 18***-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 low**
- if you suffer from **disorders of lactate metabolism**
- if you have **fructose metabolism disorders** (hereditary fructose intolerance)
- if the **volume of your body fluids is too low**
- if you have **low blood pressure**

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 adequate data from the use of CAPD/DPCA 18 in pregnant women or during lactation period. If you are pregnant, you should not use CAPD/DPCA 18 unless your doctor considers this absolutely necessary.

It is unknown whether CAPD/DPCA 18 substances/metabolites are excreted in human milk. Breast-feeding is not recommended for mothers on peritoneal dialysis.

Driving and using machines:

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CAPD/DPCA 18 has no or negligible influence on the ability to drive or use machines.

-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.

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 **low calcium level in your blood**. It may be necessary to take additional calcium-containing phosphate binders and/or vitamin D. If this is not possible a peritoneal dialysis solution with a higher calcium concentration should be used.
- if you have an **inflammation of the peritoneum**, recognisable by a 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** and **water-soluble vitamins**. An adequate diet or nutritional supplements are recommended in order to avoid deficiency states.

Your doctor will check your electrolyte (salt) balance, blood cell counts, kidney function, body weight and nutritional state.

CAPD/DPCA 18 contains 42.5 g glucose in 1000 ml solution. Depending on the dosage instructions and the pack size used up to 106.25 g glucose (CAPD, 2500 ml *stay•safe*) or 212.5 g glucose (APD, 5000 ml *sleep•safe*) are supplied to the body with each bag. This should be taken into account in patients with diabetes mellitus.

Due to the high glucose concentration CAPD 18 should be used cautiously and under monitoring by your doctor.

-Taking other medicines

Tell your doctor or pharmacist 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.

How to use CAPD/DPCA 18

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist 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.

-How much to use**Continuous ambulatory peritoneal dialysis (CAPD):**

• **Adults:** The usual dose is 2000 – 3000 ml solution four times daily depending on body weight and kidney function. After 2-10 hours dwell time the solution is drained off.

• **Children:** The doctor will determine the volume of dialysis solution required depending on the tolerance, age and body surface area of the child.

The recommended initial dose is 600-800 ml/m² (up to 1000 ml/m² overnight) body surface area four times daily.

Automated peritoneal dialysis (APD):

Bag exchange is controlled automatically by the machine overnight. For this the CAPD/DPCA *sleep•safe* system is used.

• **Adults:** The usual prescription is 2000 ml (maximum 3000 ml) per exchange with 3-10 exchanges overnight and time on the cyclor 8 to 10 hours, and at daytime one or two exchanges.

• **Children:** The volume per exchange should be 800-1000 ml/m² (up to 1400 ml/m²) body surface area with 5-10 exchanges overnight.

Use CAPD/DPCA 18 in **the peritoneal cavity only**.

Use CAPD/DPCA 18 only if the solution is clear and the bag is undamaged.

-If you forget to use it

Try to attain the volume of dialysate prescribe for each 24-hour period in order to avoid the risk of possibly life-threatening consequences. You should

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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.

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 18 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

uncommon (may affect up to 1 in 100 people):

- calcium deficiency
- 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.

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 can help provide more information on the safety of this medicine.

Storage of CAPD/DPCA 18

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 carton after “EXP”. The expiry date refers to the last day of that month.

Do not store CAPD/DPCA above 30°C. Do not refrigerate or freeze.

The solution must be used immediately after opening

Product Description**-What it looks like**

The solution is clear and colourless to slightly yellow.

The theoretical osmolarity of the solution is 509 mOsm/l, the pH is about 5.5.

CAPD/DPCA 18 is available in the following application systems and pack sizes per carton:

<i>stay•safe</i>	<i>sleep•safe</i>
4 × 2000 ml bags 4 × 2500 ml bags	2 × 5000 ml bags

Not all pack sizes may be marketed.

-Ingredients

The active substances in one litre solution are:

Calcium chloride dihydrate	0.1838 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
Glucose monohydrate (42.5 g glucose) Fructose up to 2.1 g	46.75 g

These quantities of active substances are equivalent to:

1.25 mmol/l calcium, 134 mmol/l sodium, 0.5 mmol/l magnesium, 102.5 mmol/l chloride, 35 mmol/l (S)-lactate and 235.8 mmol/l glucose.

The other ingredients of CAPD/DPCA 18 are water for injections, hydrochloric acid, sodium hydroxide.

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MAL Number

MAL07050219AZ (CAPD/DPCA 18
Sleep Safe Peritoneal Dialysis Solution)
MAL06091468AZ (CAPD/DPCA 18
Stay Safe Peritoneal Dialysis Solution)

Manufacturer

Fresenius Medical Care Deutschland
GmbH, Frankfurter Straße 6-8, 66606 St.
Wendel, Germany

Product Registration Holder

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